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Navigating the Landscape of Digital Health

Australia

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THE ACCESS AND DELIVERY PARTNERSHIP

HITAP
Health Intervention and Technology Assessment Program

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About

Research Implementation Science and eHealth Group

The Research in Implementation Science and eHealth (RISe) group is an applied research team in the Faculty of Medicine and Health at The University of Sydney. RISe is at the forefront of the emerging fields of eHealth and implementation science and our primary research emphasis is on the impact of new technologies on clinician and consumer behaviour and outcomes. With several high-profile grants and consultancies, totally over AU$13M, we aspire to be recognised as a global leader in implementation science and eHealth.

RISe works closely with a wide range of organisations, both nationally and internationally, including government departments, health service providers, professional colleges, and translational research centres. RISe pursues its mission of supporting the uptake of evidence-based care into practice by researching effective ways of implementing change in the health system; working with health systems to improve the collection and impact of health data; developing novel and high-impact educational solutions; providing consultancy and advice; and building partnerships and networks across the sector.

Menzies Centre for Health Policy and Economics

The Menzies Centre for Health Policy and Economics conducts health policy research, analysis, advice, and education.

The Centre focus on improving public health outcomes through policy innovation and practical implementation. With a program of community engagement, the Centre encourages informed debate about how Australians can influence health policy to ensure that it is consistent with their values and priorities; policies that can deliver safe, high-quality health care that is sustainable in the long term.

The Centre has a particular interest in the policy conundrums posed by the growing challenge of chronic illness. Research from the Centre has demonstrated a strong commitment to patient-centred outcomes.

EXECUTIVE SUMMARY

Australia has a history of innovation, which is reflected in the breadth of health technologies that are increasingly available in the country's digital health landscape. This breadth of digital health technologies can be categorised across four domains: Software as a Medical Device; Consumer Health Technology; Health Information Technology; and Health Communication Technology. Although there are examples of digital health in all these categories in Australia, adoption of individual solutions is patchy and there are regions of Australia with extremely limited uptake of and willingness to adopt digital health. Developing a digital health landscape that ensures the potential of digital health technologies is realised by all Australians and can be equitably and equally accessed is increasingly a focus of many organisations in Australia.

Regulation of digital health in Australia is shared across different jurisdictions consisting of federal, state and territory governments. Australia has a federal agency to govern digital health, the Australian Digital Health Agency, which is increasingly shaping the evolution of the Australian digital health landscape. The broad priorities of the Australian Digital Health Agency are ensuring health information is accessible, safely and securely, to all stakeholders; collection of high-quality health data; improved accessibility, quality, safety and efficiency of health care through digitally enabled care models; and a digitally capable workforce. All states and territories have their own digital health strategy, which generally reflects the priorities of the Australian Digital Health Agency.

The Australian digital health landscape is seeing a growth in technologies entering the market, with an increasing volume of digital health solutions seeking regulation over the last decade. A number of these technologies have undergone Health Technology Assessment, to be considered for reimbursement by the Australian government via the Medicare Benefits Scheme. Coupled with this, the federal government has invested in incentive schemes to encourage the adoption of new digital health technologies in routine practice, and to ensure these technologies are integrated with digital health infrastructure such as the national Electronic Health Record. These schemes reimburse health professionals who invest in software that complies with key specifications to support integration with key digital health infrastructure.

There are many stakeholders in the Australian digital health landscape. At the centre of this stakeholder group is the patient, who is the ultimate beneficiary of a digitally enabled healthcare system that is efficient, safe and of high quality. Other stakeholders include government agencies and peak bodies; researchers and academics; advocacy groups and not-for-profits; industry and more. To fully realise the potential of digital health in Australia, all stakeholders need to be more collaboratively engaged to identify gaps, overcome challenges, and realise opportunities that come from the integration of technology in healthcare.

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1. BACKGROUND

Overview of the digital health ecosystem

Australian Health System

The Australian Health System is considered one of the best in the world and generally serves the Australian population well (1, 2). Australia's health system compares favourably to similar health systems on care outcomes and administrative efficiency (3). As a nation, Australia has one of the longest life expectancies, in part due to the nature of its healthcare system which provides quality, safe and affordable healthcare (2).

The Australian health care system consists of various providers at different levels including nurses, allied health workers, medical specialists, and primary care services delivered by general practitioners (GPs) (1, 2). As of 2019 – 2022, Australia had 695 public hospitals, 182 of which were in major cities: 402 in inner regional and outer regional areas and 111 in remote area serving total population of 25.69 million people (4). On an average day, there are 30,500 hospitalisations in public and private hospitals across the country. The majority of these hospitalisations are for acute medical care. In addition to hospitalisations, there are approximately 105,000 services provided to non-admitted patients. These services include consultations with medical practitioners, provision of diagnostic or other procedures, and allied health or clinical nurse specialist services. Although there is a spread of hospital facilities across the country, 67% of hospital beds are in major cities (4).

The Australian health system is experiencing growing demand for services, as evidenced by increased in-patient and outpatient presentations to public hospitals in the last five years and growing numbers of emergency presentations due to an ageing population (3). It is expected this demand will grow in future, driven by an ageing population, which will add strain to the system (1, 2).

Universal Healthcare

Since 1984, Australia has had a universal health care scheme, which means most of the country's health care is provided for free or is highly subsidised (5). This healthcare is provided to all Australian and New Zealand citizens, permanent residents, and people in Australia from countries with reciprocal agreements through Medicare. Medicare has three major parts including: Hospitals, Medical Services and Medicines respectively.

Hospitals

In Australia, hospital care can be provided by both public and private hospitals (4). Public hospitals are provided funding by the Australian government but are generally owned, funded, and administrated by state and territory governments. In 2019-2020 there were 695 public hospitals in Australia. Australia also has Private hospitals which are managed by either for-profit or not-for-profit organisations. Private hospitals in Australia also indirectly receive a subsidy through government subsidy of private health insurance. In 2019-2020 there were 657 private hospitals in Australia, including day hospital facilities. Medicare covers the cost of all public hospital services for anyone who meets the eligibility criteria described above (2).

Medical Services

In addition to hospital-based services, the Australian health system includes services that are non-hospital-based. This includes primary care and ambulatory specialist care. Most of the primary medical care services are provided by private general practitioners with Australia's 31 Primary Health Networks (PHNs) responsible for coordinating health services in local areas within states and territories. PHNs provide a range of non-hospital health services that are needed locally including mental health services and health promotion programs. Ambulatory private specialist services including diagnostic, pathology and procedural services are subsidised by the Australian Government through Medicare via the Medicare Benefits Schedule (MBS) (6). Medical and other clinical services are considered for listing on the MBS on the advice of the Medical Services Advisory Committee (MSAC) which uses formal health technology assessment (HTA) as part of its decision-making.

Medicines

The Australian government subsidises the cost of medicines for individuals enrolled in Medicare. The main system for subsidising medicines is known as the Pharmaceutical Benefits Scheme (PBS) (7). Medicines are considered for listing on the PBS on the advice of the Pharmaceutical Benefits Advisory Committee (PBAC) which uses formal HTA as part of its decision-making.

Digital Health in Australia

Definition of digital health

Digital health describes a breadth of health technologies, and the health services the technologies can be used to support. In Australia, like in many countries, there are many different definitions of digital health proposed by the myriad stakeholders in the field. Definitions of digital health used by key organisations in the Australian digital health landscape are summarised in Table 1.1.

A key theme that emerges across all definitions of digital health in Australian policy is an emphasis on health information exchange, with many definitions emphasising the safe and secure use of health data. There is also a notable emphasis on using digital technology to support connection and communication in many jurisdictional definitions. Some definitions of digital health go beyond describing the technology and include the use of these technologies for health service delivery and delivery of healthcare. Notably, most definitions of digital health in Australian policy documents only refer to the use of health technology to treat patients, not for testing patients. This is an issue because this means many policy documents exclude a major area of digital health technologies that are beginning to be implemented in Australia.

Table 1.1: for an overview of Digital Health definitions in key policy documents[1].

Organisation	**Definition**
Australian Institute of Health and Welfare (8)	"An umbrella term referring to a range of technologies that can be used to treat patients and collect and share a person's health information, including mobile health and applications, electronic health records, telehealth and telemedicine, wearable devices, robotics and artificial intelligence."
Australian Digital Health Agency (9)	"Digital health is about electronically connecting the points of care so that health information can be shared securely. This is the first step to understanding how digital health can help deliver safer, better-quality healthcare."
Australian Commonwealth Department (In the context of health technology assessment) (10)	"Using technology to improve the healthcare system for providers and patients alike."
Victorian Department of Health (11)	"The uses of information technology/electronic communication tools, services and processes to deliver health care services or to facilitate better health. Increasingly, it encompasses the provision of tools and information to empower patients to better understand and manage their health and the health of their family."
Queensland Health (12)	"Includes the use of information and communication technologies (ICT) for health including treating patients, conducting research, educating the health workforce, tracking diseases and monitoring public health (World Health Organisation, 2004)."
Northern Territory (13)	"Digital health is 'the field of knowledge and practice associated with the development and use of digital technologies to improve health'. (WHO Global Strategy on digital health 2020-2024). Digital health involves the use of information and communication technologies (ICT) for health care including treating patients, conducting research, educating the health workforce, tracking diseases and monitoring public health. (WA Health Digital Strategy 2020 – 2030)."

Western Australia (14)	It "involves the use of information and communication technologies (ICT) for health care including treating patients, conducting research, educating the health workforce, tracking diseases and monitoring public health."

[1] *All definitions with quotation marks have been extracted directly from the source material referenced in the left column.*

Categories of Digital Health technologies in Australia

Australia's health sector has a long history of using innovative technologies to improve healthcare delivery. In Australia, the digital health landscape encompasses many varied technologies. These technologies are used in different contexts by different stakeholders, including for managing health and well-being, supporting health service delivery, and enabling precision care. Due to the diversity of the technologies themselves and their possible uses, these technologies have different risk profiles for their ability to impact health and well-being (15). Key categories of digital health are described below.

Software as a Medical Device

Software as a Medical Device (SaMD) can be defined as medical devices that incorporate software or are software or are software that relies on particular hardware to function as intended (16). Examples of these technologies include remote monitoring cardiac devices, Total Body Photography (TBP) used for monitoring certain health conditions and some categories of disease tests.

Consumer Digital Health

Consumer digital health is a broad area that describes a large number of technologies that can be used by the community to support health and well-being and manage health conditions. A large portion of consumer digital health falls under the umbrella term mobile health (mHealth) which describes the use of mobile devices to monitor or detect biological changes in the human body, while device management entities, such as hospitals, clinics, or service providers, collect data and use them for healthcare and health status improvement (17). Examples of Consumer digital health include smartphone and web applications for tracking diet, mental health, exercise, and a wide variety of other activities to maintain a healthy lifestyle. It also included dedicated devices such as smart watches for monitoring activity and other data points.

Health Information Technology

This category of digital health describes technologies that can collect and use data to improve health and health services (18). These technologies are frequently used by the health workforce rather than directly by consumers and can include Electronic Health Records (EHRs), Electronic Medical Records (EMRs), Clinical Decision Support Tools, electronic prescribing systems, practice management software, and patient administrative systems.

Telecommunication Technology

Telecommunication technologies in the context of health and healthcare can be described as those which facilitate communicative encounters between health stakeholders (18). Examples of these technologies include telehealth and telemedicine, virtual care and in some instances the use of emerging technologies such as virtual repair to enable real or non-real-time interactions between different groups of health stakeholders.

2. DIGITAL HEALTH STAKEHOLDERS

Definition and roles of stakeholders

The Australian digital health landscape has a large number of stakeholders. These include health professionals, consumers and carers; government agencies, peak bodies and legislators; researchers and academics; and not-for-profit and advocacy agencies (19). Australia also has a growing digital health industry sector and as such our landscape includes software and device vendors; entrepreneurs and other industry groups (20).

Government Agencies, Legislators, and Policy Bodies

Each jurisdiction has a Department or Ministry of Health that is overseen by the respective Minister for Health. This Department oversees the entire public health system. The Minister for Health and their government can also introduce or amend legislation to regulate digital health technologies and services that are non-government owned or part of the private health system.

Some jurisdictions also have independent agency that manages digital health such as Australian Digital Health Agency, eHealth Queensland and eHealth New South Wales. Other jurisdictions have agencies, bodies and boards embedded in the Department of Health that manages digital health.

The Commonwealth Government has also introduced legislation and established national laws in collaboration with state and territory governments to regulate privacy, medical device regulation and consumer protections. These national laws often have independent agencies in charge of monitoring and enforcing compliance. These agencies also release guidelines and policies to support individuals and groups affected by these national laws.

Researchers and Academics

Universities, cooperative research centres and science agencies (e.g., CSIRO) can help provide solutions about facilitators and challenges relating to the introduction, use, implementation, and evaluation of digital health technologies. Research and academia also play a vital role in identifying strategies and creating curricula to upskill the health workforce.

Consumers and Community

Digital consumers are individuals who buy and sell digital products and services. Digital health consumers in Australia can also include individuals who engage with digital health services and technologies without direct payment given our universal healthcare scheme.

Digital health technologies and services can also impact the wider community as individuals can remotely access their health information without contacting their treating health professional or needing health care. The community is defined as all individuals who reside in Australia or have had their health information collected and/or stored in Australia.

Industry Groups

Industry groups are manufacturers, sponsors and/or vendors of medical devices, software-based medical devices and other digital health technologies. It also includes existing and emerging digital (health) enterprises that service the health sector. For example, cloud-based storage can be used by many industries but may benefit the health sector by improving the interoperability of medical records.

Peak Bodies

Peak professional bodies in Australia include Royal and Professional Colleges, Boards of Registered Health Practitioners, and other representative bodies. These bodies advocate for their members, set codes of conduct and establish requirements for accreditation, registration and professional development.

A full list of Health Practice Boards can be found here (21).

Health Workforce

Includes clinical and non-clinical staff who will be involved in the delivery of health services using digital technologies e.g., online appointment scheduling, telehealth etc. It also extends to Health Executives, Government Agencies, Legislators and Boards responsible for the implementation and evaluation of digital strategies.

The ADHA is focused on creating a values-based culture from leadership to staff to help propel Australia's digital vision forward. This culture will be designed to encourage collaboration and empower participation in digital health (22).

There are eight specific digital profiles that "articulate the expectations of the health workforce" (23) in the age of digital health:

- Patient, consumer, and carer
- Frontline clinical
- Digital champion
- Clinical and technology bridging
- Technologist
- Leadership and Executive
- Business, Administration and Clinical Support
- Education and research

Healthcare Organisations

Healthcare organisations refer to public and private businesses or associations that provide healthcare services to the Australian public. Examples include sole medical practitioners, dental clinics, public hospitals, and private specialist surgeries. It also includes some organisations and executive bodies that facilitate the delivery of digital health care products and services. These are Executive Boards, Health Districts, Primary Health Networks, Hospitals Health Services etc. that service a geographical area.

Not-government Organisations

Many non-government organisations operate internationally and assist vendors, consumers, and practitioners as they navigate the digital health landscape.

Not-for-profit organisations have strong connections to their communities which can be leveraged by Health Departments, Legislators and Government Agencies to provide public education and enhance digital literacy skills in the community. These organisations also create a feedback loop between health organisations and the community. Examples include The Good Things Foundation and The Centre for Culture, Ethnicity, and Health. The World Health Organisation has also developed a *Global Strategy for Digital Health 2020-2025*. This strategy focuses on promoting "equitable, affordable and universal access" (24) to the benefits of digital health.

Other non-government organisations help create solutions to make better use of digital health technologies and support individuals operating in the digital health landscape. For example, ANDHealth, founded in 2017, helps mid-stage companies navigate systematic barriers to commercialisation and accelerate their ability to access institutional investment in global markets. Meanwhile, the Consumer Health Forum of Australia advocate for safe and quality healthcare for Australian consumers, especially equitable access to health services and information.

3. LEGAL AND REGULATORY FRAMEWORKS

National, state and territory digital health strategies

As a federation, there are nine separate jurisdictions in Australia including six states, two federal territories and the Commonwealth or the federal government. Each jurisdiction has developed its own digital health strategy (see Table 2.1 below).

Table 2.1: Overview of the key digital health strategies, regulations, and standards that make up the Australian landscape.

Jurisdiction	Digital Strategy and Related Regulations, Frameworks and Standards	Organisation(s) or Entities
National		
Commonwealth	Australia's National Digital Health Strategy: safe, seamless and secure: evolving health and care to meet the needs of modern Australia (25) (August 4, 2017) Related Regulations, Frameworks and Standards: • National Digital Health Workforce and Education Roadmap (23) • National Digital Mental Health Framework (June 2021) (26) • National Safety and Quality Digital Mental Health Standards (2020) (27) • Therapeutic Goods Act 1989 (Cth), Therapeutic Goods Regulations 1990 (Cth), Therapeutic Goods (Medical Devices) Regulation 2002 (Cth) • Privacy Act 1988 (Cth)	Australian Digital Health Agency
States		
New South Wales	eHealth Strategy for New South Wales Health 2016-2026 (28) (May 6, 2016) Related Regulations, Frameworks and Standards: • New South Wales Artificial Intelligence Assurance Framework (29) • Artificial Intelligence Policy Framework (30) • Artificial Intelligence Strategy (31) • North South Wales Health Analytics Framework (2016) (32) • New South Wales ICT Assurance Framework (February 2017) (33) • New South Wales Health Strategic Framework for Integrating Care (November 2018) (34) • Sydney North Health Network Digital Health Strategy (35)	eHealth NSW

	• Central and Eastern Sydney Primary Health Network Digital Health Strategic Plan (2019-2021) (36) • North Sydney Local Health District Digital Strategy 2021-2026 (37) • New South Wales Digital Government Strategy (38)	
Victoria	Victoria's Digital Health Roadmap (11) (September 19, 2021) Related Regulations, Frameworks and Standards: • Digital Health Capability Framework for Allied Health Professionals (39) • Peninsula Health, Digital Health Strategy (2021-2025) (40) • Gippsland Primary Health Network, Digital Health Guide (41) • Digital Health Standards and Guidelines including the ePrescribing guide, eReferral standard, Virtual Care Standard and Guide and Victoria's Digital Health Maturity Model • Victorian Agency for Health Information Strategic Plan (2019-2022)	Department of Health
Queensland	Digital Health Strategic Vision for Queensland 2026 (12) (March 27, 2017) Related Regulations, Frameworks and Standards: • Gold Coast Primary Health Network Strategic Plan (2021-2023) • eHealth Investment Strategy (August 2015)	Queensland Health
South Australia	South Australia Health Digital Strategy (42) (September 2017) Related Regulations, Frameworks and Standards: • Health and Wellbeing Strategy 2020-2025	Digital Health SA Board
Western Australia	Western Australia Health Digital Health Strategy 2020-2030 (14) (October 2019) Related Regulations, Frameworks and Standards: • Western Australia Nursing and Midwifery Digital Health Strategy (43) • Digital Strategy for the Western Australian Government 2021-2025 (44)	WA Department of Health

Tasmania	Digital Health Transformation – Improving Patient Outcomes 2022-2032 (45) (25 March 2022) Related Regulations, Frameworks and Standards: • Tasmanian ICT Workforce Action Plan 2020-2023 (46) • Our Digital Future: Tasmanian Government Strategy for Digital Transformation (March 2020) (47) • Our Digital Future Strategic Action Plan (May 2020) (48) • Our Healthcare Future: Advancing Tasmania's Health (Draft) (June 2022) (49)	Department of Health
Federal Territories		
Northern Territory	Strengthening Our Health System Strategy 2020-2025 (13) (December 2020) Related Regulations, Frameworks and Standards: • The Northern Territory Health Virtual Care Strategy (50)	Northern Territory Health, Aboriginal Medical Services Alliance Northern Territory, Northern Territory PHN
Australian Capital Territory	Digital Health Strategy 2019-2029 (51) (26 August 2019) Related Regulations, Frameworks and Standards: • Australian Capital Territory Health Quality Strategy 2018-2028 (52) • Australian Capital Territory Health Clinical Governance Framework 2018-2023 (27 June 2018) (53)	Digital Solutions Division

The National Digital Health Strategy, released in 2016, proposed seven strategic outcomes to be achieved by 2022: (25)

i. Health information that is available whenever and whatever it is needed
ii. Health information that can be exchanged securely
iii. High-quality data with a commonly understood meaning that can be used with confidence
iv. Better availability and access to prescriptions and medicines information
v. Digitally enabled models of care that drive improved accessibility, quality, safety and efficiency
vi. A workforce confidently using digital health technologies to deliver health and care
vii. A thriving digital health industry delivering world-class innovation

The national strategy was developed after an extensive consultation process with key stakeholders including consumers, healthcare workers, professional bodies, and community groups (54). These outcomes are focused on building capacity in the Australian healthcare system through investment in workforce education and high-quality digital infrastructure. Features of digital infrastructure include improved interoperability of clinical data, detailed and standardized data collection, digital medication management, and the widespread use of digital technologies for patient care and communication. Workforce and education training will focus on improving provider confidence with digital technologies to enhance provider willingness and readiness to use digital technologies and communication channels.

The Australian Digital Health Agency (ADHA), a corporate Commonwealth entity, released the national digital health strategy in fulfilment of its vision for "a healthier future for Australians through connected healthcare" (55). The ADHA supports the achievement of these outcomes through collaborations with consumers, healthcare workers and the industry. For example, in collaboration with the Australian Medical Council (AMC), the ADHA released a Capability Framework on digital health in Medicine in 2021. This Framework explores how education providers can support the development of a digitally competent workforce in Australia and New Zealand (56). The ADHA also monitors progress towards outcomes and standards set by the national strategy through periodic reports on interoperability and data quality (57).

States and territories have focused on the implementation of specific technologies in their strategies to help facilitate the transition to digitally enabled models of care and have prioritised the use of centralised EMRs accessible to patients and the wider multidisciplinary team. This includes enhancing interoperability across information systems and the integration of additional services such as eReferrals, telehealth and virtual care. All jurisdictions are also exploring the use of mHealth applications and the automation of workflows using robotics and artificial intelligence (AI). The integration of emerging technologies however is still dependent on the initiative of individual practitioners, practices, or organisations. Table 2.2 below provides a more detailed breakdown of each strategy.

Table 2.2: Detailed overview of Australian digital health strategies described by jurisdiction.

Jurisdiction	Strategy
States	
New South Wales	eHealth Strategy for New South Wales Health 2016-2026 (28) The eHealth Strategy has seven focus areas that constitute the digital landscape. Five of these areas are based on the introduction or integration of digital health technologies or information systems. The other two areas involve using data in medical decision-making and fostering "a culture of innovation and collaboration". This strategy prioritises the digitisation and centralisation of core clinical systems including medical records, incident management systems and workforce management tools (e.g., payroll, supply chain and remote work). Part of this digitisation process is ensuring the core clinical systems are secure, private, and connected to high-speed networks. A single sign-on authentication process will be used across the health system. These improvements are also designed to create a mobile workforce that can access real-time information at any time or location. It also strives to integrate digital care by expanding telehealth services and eReferrals capabilities while standardising the use of secure online messaging and eScheduling. More long-term solutions to direct primary care traffic away from hospitals include managing chronic conditions remotely using wearables and robotics. In addition, this strategy is interested in the proactive management of health in the community through the use of real-time analytics from wearables, mobile applications, and data linkage.
Victoria	Victoria's Digital Health Roadmap (11) There are five concrete outcomes pursued by the Victorian Department of Health. These outcomes are focused on creating a patient-centred care model in the health system by centralising patient records, streamlining patient access to health information and expanding options for care at home. Digital infrastructure implemented in pursuit of this care model will be monitored for cybersecurity and supported by a state-wide network, disaster recovery and legacy server replacements. Improvements to this effect have received an AU$100 million investment over the last five years. Core clinical systems will be established across the state including standardised EMRs, eScheduling for appointments, procedures, and tests as

well as patient and consumer portals. Flexible and remote patient care will be supported with more telehealth and virtual care services and single patient identifiers. Patient education will be encouraged by creating a framework to identify and recommend secure and evidence-based mHealth applications. Information sharing among clinical staff will be supported through eReferrals, eDischarge, an image-sharing program and decision-support programs integrated with various programs.

Most of these initiatives are in progress or planned.

Queensland

Digital Health Strategic Vision for Queensland 2026 (12)

This vision is designed to achieve eight strategic goals along three horizons. These horizons are building a sustainable digital health system, optimising workforce capabilities, and enabling transformations to models of care. The eight goals target greater patient engagement and monitoring, integration of core clinical systems and harness information for learning, decision-making support, and system improvements.

Queensland has adopted an interactive approach to patient engagement with a focus on gamifying wellness outcomes for patients with rewards and incentives. There will also be extensive use of online and digital health resources such as consumer wearables and mHealth applications. Patient care will be increasingly digitised with the expansion of telehealth services and remote patient monitoring, integration of system-wide EMRs and My Health Record and the creation of digital hospitals. Single patient identifiers and sign-on authentication for staff will be introduced.

Access to information will be improved with automated workflows, eReferrals, eScheduling, and investments in infrastructure to support a mobile workforce. Data will also be extracted from these technologies and systems to learn more about the community, patient care and workflows. Data analytics will assist in personalising care for patients in the community while clinical data repositories will be created for population planning and analysing performance.

South Australia

South Australian Health Digital Strategy (42)

This Strategy is focused on establishing a shared health record, expanding telehealth services, and enabling secure information sharing across settings. This includes supporting eReferrals, eDischarge, and the integration of My Health Record.

Western Australian

Western Australian Health Digital Health Strategy 2020-2030 (14)

Western Australian Health is pursuing six strategic themes intending to empower consumers, a digitally capable workforce, enhance public health and incorporate innovation and research. Ten design principles underlie these themes including safety, security, person-centred approach, evidence-based decision making and sustainable user-centred design. The primary outcome is the establishment of state-wide EMRs.

Other digital initiatives being implemented include expanding telehealth and virtual care services, remote patient monitoring, centralised human resource, workforce, and communication systems. Western Australian Health also aims to integrate eReferrals, centralised laboratory information systems and an online learning management system. More novel technologies being adopted are patient and employee portals augmented and virtual reality and a 24-hour operations centre. Portals are designed to enable increased access to information for patients and staff. Patients would also be able to schedule appointments, receive personalised health

	education and access test results. The operations centre would enable patient management across the health system using real-time data, predictive analytics, and artificial intelligence. Research and innovation will be supported with data linkage to identify areas of concern and predict risk factors in the community. Digitally enabled models of care will be streamlined by updating relevant legislation and policies and increasing resources for security, governance, and reporting.
Tasmania	Digital Health Transformation – Improving Patient Outcomes 2022-2032 (45) This digital health transformation is focused on improving patient and community care by optimising clinical integration and fostering state-wide collaboration across settings and specialities. Eight key principles guide the implementation of digital health technologies and services. These principles are overwhelmingly focused on collaborating with clinicians and patients to deliver timely care that is responsive to the needs of the population. The responsiveness and adaptability of the healthcare system will be driven by leveraging digital health solutions and innovations to improve patient care. One outlier principle focuses on keeping patient data private and secures through cybersecurity and privacy legislation and regulations. These outcomes are designed to be achieved across three horizons that incrementally build upon each other over ten years. Horizon One focuses on increasing access to health information systems and expanding digital capabilities. Initiatives under this Horizon include enhancing information and communication technology infrastructure, interoperability, eReferrals, and expanding telehealth and virtual care. Other priorities include standardising clinical workflows and correspondence in EMRs, improving staff digital literacy and leveraging other digital initiatives such as My Health Record. Horizon Two seeks to further enhance telehealth services across settings and electronic medical record integration. Initiatives include digitising administrative and operational workflows, introducing patient portals for personal information management and booking appointments as well as expanding clinical and medication decision support. Horizon Three focuses on leveraging artificial intelligence and machine learning to optimise and personalise care in the community. Digital initiatives prioritised in this Horizon is establishing a state-wide single-patient portal for appointment scheduling and workflow management. More specific solutions include precision medicine, biobanking and genomics as well as augmented intelligence training for staff. While workflows and treatments are increasingly digitised and augmented, clinical staff will be encouraged to incorporate social determinants of health into their care.
Federal Territories	
Northern Territory	Strengthening Our Health System Strategy 2020-2025 (13) This collaborative strategy is focused on four goals: building healthier communities, enabling the workforce, connecting the health system, and harnessing innovation. The first two goals are centred on patient and staff education through online learning platforms and digital health literacy campaigns. The use of technology by these populations will also be maximised by expanding telehealth services, integrating My Health Record

		and implementing secure messaging. Likewise, a workforce plan will be developed to encourage the uptake of digital health technologies. The wider health system will be connected using a single territory-wide electronic patient record and integrating existing systems. This process will be completed by a private contractor. Standardised legal and ethical frameworks will also be adopted to govern patient security and data security and privacy. Innovations in digital health will also be monitored and implemented to meet the needs of Northern Territory communities and the health system. Academic institutions and multi-disciplinary teams will also be engaged to translate health systems research and sustain the use of innovations.
Australian Capital Territory		Digital Health Strategy 2019-2029 (51) There are three strategic themes underlying the Australian Capital Territory's approach to digital health: patient-centred care, health services enabled by digital health technologies and innovation and collaboration. These themes are stratified across three strategic goals to improve access to healthcare, accountability in decision-making and securing a sustainable model for health services. The Australian Capital Territory has also prioritised the development of a single territory-wide patient record that can be accessed remotely by all health services (e.g., public/private, disciplines and organisations) as well as the integration of My Health Record. The Health Department also aims to minimise non-clinical tasks for clinical staff by automating administrative tasks and communication. Research into data linkage and the development of legal and ethical frameworks will be conducted in collaboration with health facilities, technology, and educational partners. Other long-term outcomes include preventative health management, standardised use of data analytics and targeted early interventions. The territory also endeavours to invest in augmented reality and machine learning.

Regulatory Framework

Governance structure, process, and core functions

Each jurisdiction has its governance structure. All state and territory jurisdictions collaborate with the ADHA to achieve outcomes in the national digital health strategy and coordinate the integration of My Health Record (an EMR that records variable amounts of health data for each enrolled individual). All jurisdictions have also emphasised the importance of collaborating with other departments, multidisciplinary clinical teams, and consumer and industry groups. Only some have officially included these groups in their organisational structure. The following section provides an elaborate account of the governance, processes, and functions within the Commonwealth. Detailed descriptions of the governance structures for all states and territories can be found in Appendix 1.

The Commonwealth

The ADHA is a corporate Commonwealth entity (58). This means that the ADHA is a separate legal person from the Commonwealth government. It can enter contracts, own property, and exercise other legal rights available to other legal persons (59). The ADHA was established under *Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016* (Cth) ('the Rule'). The Rule details "the purpose, functions, powers" of the ADHA as well as its organisational structure, reporting obligations and staffing arrangements (60). Interestingly, the ADHA is jointly funded by the Commonwealth (approx. AU$200 million) and the states and territories (approx. AU$34 million) (61).

The Health Minister for the Commonwealth government can give written directions to the ADHA relating to "the performance of its functions or the exercise of its powers" (60). These directions require approval from Health Ministers in every jurisdiction. Once issued, the ADHA **must** comply with the direction. The Health Minister also appoints the ADHA Board and its members. Board members must have skills and experience in relevant fields such as medical practice, digital

health systems and consumer advocacy. Their combined knowledge and expertise must also cover corporate governance, financial literacy, and risk management. The Board Chair cannot be engaged in other paid employment without approval by the Minister while Members must not have paid roles that could or do conflict with the performance of their duties as determined by the Health Minister as per official Workplace Relation Act.

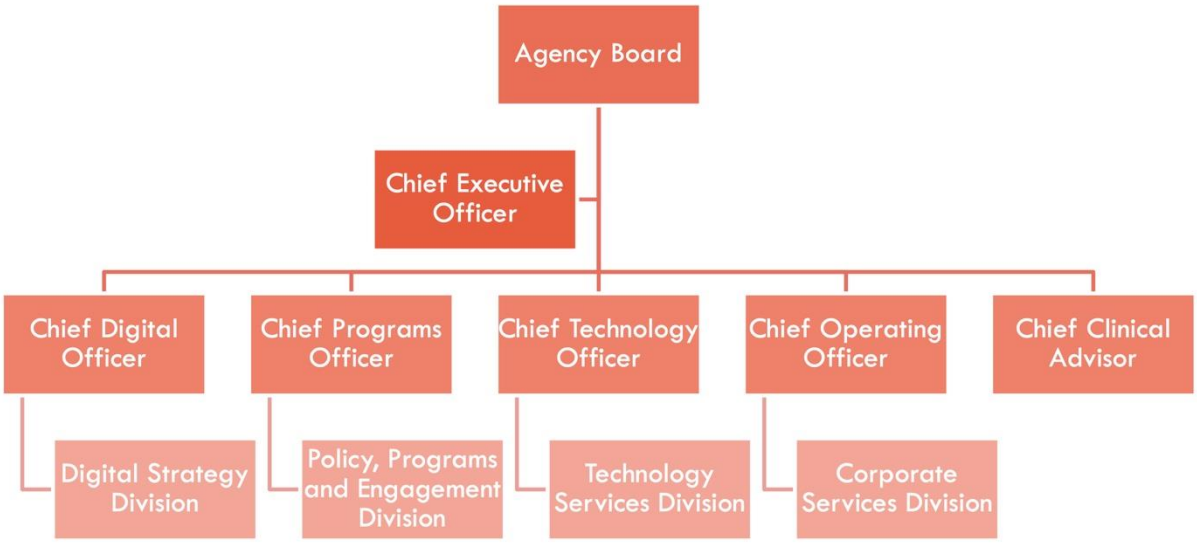
The ADHA Board is the accountable authority of the ADHA and is responsible for deciding on "objectives, strategies and policies" (60) and ensuring proper performance of their functions. It is empowered to do all things necessary to fulfil its responsibilities under the Rule including the power of delegation to Board members or the Chief Executive Officer (CEO). The Board is also responsible for appointing members of the four standing advisory committees created under the Rule to ensure industry engagement. The four Advisory Committees are titled Clinical and Technical, Jurisdictional, Consumer and Privacy and Security. The functions of each Committee are set out in items 45-51 of the Rule. Charters outlining the purpose, scope, membership and responsibilities of each Advisory Committee can be found here (62). The Board can establish any other advisory committee as needed.

The Board is further required to develop an annual national digital health work program. This program addresses digital health infrastructure, services, and foundations and helps facilitate information sharing using these resources across Australia. Examples include My Health Record, Healthcare Identifiers Service, Secure Messaging Delivery and more (60).

The Rule specifies that there must be a CEO of the ADHA (Part 7). The CEO is responsible for the day-to-day administration of the ADHA and can do all things necessary to perform this role. Any actions taken by the CEO in fulfilment of their responsibilities are taken to be done by the ADHA. The CEO **must** comply with the direction and policies issued by the Board. Any outside employment must be first approved by the Board and the Health Minister must be notified.

The ADHA Executive team consists of the CEO, four Chief Officers and a Chief Clinical Advisor. The four Chief Officers oversee their divisions and are directly answerable to the CEO under the current organisational structure of the ADHA (See Figure 1). The four divisions are digital strategy, policy, programs and engagement, technology services and corporate services. These Officers oversee branch managers who are responsible for various aspects of the division. For example, the Technology Services division has branch managers for technology operations and information technology services. Figure 1 illustrates the organisational structure.

Figure 1. ADHA Organisational Structure (10 May 2022) (63)



The Rule also requires the ADHA to work collaboratively with governments, peak professional bodies, consumer representatives, health organisations and the digital technology industry in other and across jurisdictions (60). Health Ministers from each jurisdiction can request access to documents or information about the ADHA's activities and operations. Any reports or documents the ADHA is required to produce under the Rule must be made available to the Health Ministers (60).

Primary Health Networks

- There are 31 PHNs across Australia that are responsible for coordinating primary and community care (64). PHNs are independent bodies responsible for tailoring health services to the demographics and health needs of people living in each PHNs geographical region. Each PHN has a Board that oversees the execution of its responsibilities (65). The Commonwealth government provides funding to these networks based on their

performance as assessed against national and local indicators (66). These indicators are focused on the quality of care provided by health services, accessibility of services, care coordination and long-term change (66). Many of these networks have their digital strategies as listed in Table 2.1.

Regional regulatory frameworks are described in detail in Appendix 1.

Legal frameworks/mandates

The legal and regulatory framework that governs digital health in Australia is technology neutral. That is, the legislation is designed to be non-specific and adaptable to innovations and technological advancements. There are three key pieces of legislation that regulate digital health technologies. There are also separate statutory authorities responsible for the regulation and enforcement of each piece of legislation.

It should be noted that one consequence of a technology-neutral approach to innovation is that there are no requirements that certain equipment or technology platforms be used in healthcare. It is sufficient that digital health technologies meet the minimum standards of safety and quality across industries. This minimises consistency in practice, complicates interoperability between different providers and settings and makes it more difficult for consumers who must master different applications. The ADHA has however published resources to help healthcare staff and professionals navigate the digital landscape with simple explanations and case studies (84).

Privacy Act 1988 (Cth) (Privacy Act) (85)

The Privacy Act introduces 13 privacy principles, or APPs, that outline how health data should be collected, used, stored, and disclosed. Compliance is mandatory for private and public agencies or organisations that provide health services and/or hold information. Third parties, irrespective of their country of origin or operation, that collect data or provide health services to a person physically present in Australia are also bound by the APPs. Specifically, health services are required to develop a privacy plan that clearly explains how health information will be managed. This plan must be freely available.

Health data includes information or opinions about an individual's health or services rendered, personal information collected to provide a health service and genetic information relating to the health of the individual. Health services are broadly defined to include any activity performed in relation to an individual's health, diagnosis, or treatment. This covers medical practitioners, allied health, complementary therapists, gyms, and educational institutions.

Health data is characterised as sensitive information and consent must be given before it can be collected. This consent can be expressed or implied, but it must be reasonably necessary for the organisation to collect this information to perform its activities. The Commonwealth Government is evaluating whether an unambiguous expression of consent should be mandated (86). Individuals must be made aware of who is collecting the information and why information is being collected and possible disclosure of information to overseas recipients. Individuals must otherwise have the option to not identify themselves or use a pseudonym. If information is freely offered by an individual, the health service provider must decide whether it is reasonably necessary to collect the information.

Once collected, health information should only be used or disclosed for the purpose for which it was collected. Disclosure for another purpose is permitted with the individual's consent or if the individual would reasonably expect the information to be used or disclosed for another purpose (e.g., specialist referrals). The APPs explicitly ban the use or disclosure of health information for direct marketing without consent or overseas recipients that do not comply with APPs or similar privacy principles. This is a growing risk as many digital health technologies are hosted or developed by organisations overseas that often reserve the contractual right to use deidentified data for commercial purposes such as advertising.

Likewise, health services must take reasonable steps to protect health data. Information stored must be accurate, up-to-date, and complete. Individuals must also have the option of dealing anonymously with health services unless otherwise required by law. The complexity of digital health technologies however has created an emerging risk of deanonymisation when data sets are linked across platforms. One approach promoted by government initiatives, such as My Health Record, is the use of healthcare identifiers and Medicare numbers. These options remove personal identifiers such as age or date of birth while coordinating care across services with a single unique identifier for patients. The use of healthcare identifiers is governed by the *Healthcare Identifiers Act 2010* (Cth) and *Healthcare Identifiers Regulations 2020* (Cth) (86). These Acts specify that identifiers can only be used for limited purposes similar to health data and non-permitted collection, use or disclosure is subject to civil and criminal penalties.

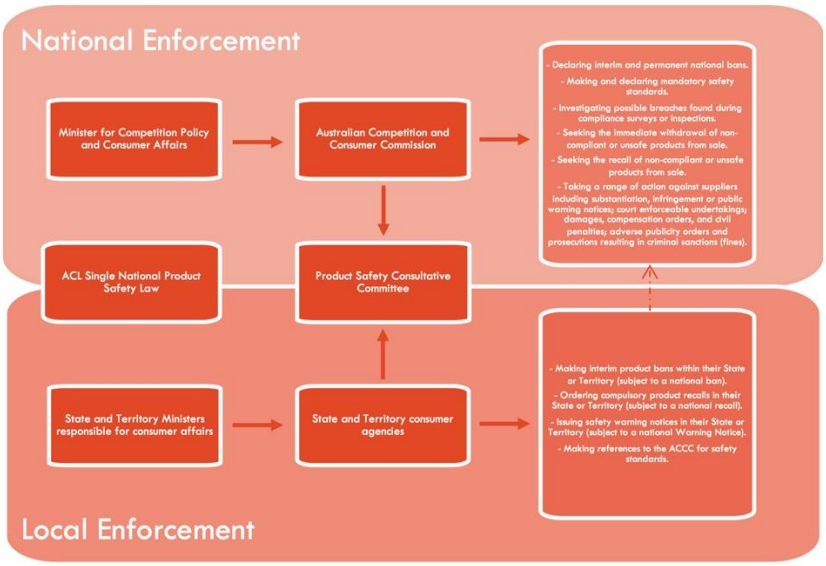
Breaches of APPs are also subject to regulatory action and penalties. The Privacy Act empowers the Privacy Commissioner and, by extension, the Office of the Australian Information Commissioner (OAIC) to investigate and enforce privacy

breaches. The OAIC prefers to facilitate voluntary compliance with privacy obligations through best practice guidelines, public education on privacy rights and obligations, and proactive monitoring of compliance with privacy obligations (87). There are also coercive powers available to the OAIC when responding to alleged interferences with privacy. These powers include the ability to investigate or decline to investigate, complaints, conciliate or refer complaints and demand the production of relevant evidence or the presence of persons involved in the complaint (87). Failure to attend according to an OAIC direction is an offence (87). Likewise, data breaches that are likely to result in serious harm must be immediately reported to affected individuals and the OAIC. A complaint is not necessary for an investigation to be conducted into alleged breaches of the Privacy Act. When deciding on a complaint or alleged contravention, the OAIC can issue enforceable undertakings, seek injunctions and/or apply for civil penalties. Civil penalties are also commonly sought for serious or repeated interferences with privacy. The OAIC will consult factors outlined in its *Privacy Regulatory Action Policy* when selecting the appropriate regulatory action (87).

Competition and Consumer Act 2010 (Cth) (88)

The *Competition and Consumer Act 2010* (Cth) (CCA) enforces fair trading and competition in the market. It sets out rules relating to product safety, price monitoring, industry codes and regulation and mergers and acquisitions. The CCA also sets out the *Australian Consumer Law* in Schedule 2 ('ACL'). The ACL was a product of cooperation between jurisdictions to create one law for consumer protection. Figure 6 depicts the regulatory framework behind the ACL. It covers misleading or deceptive conduct, unconscionable or unfair dealings, conditions and warranties, manufacturer liability and product safety and information. Businesses are, as a result, bound by the same obligations and responsibilities, as outlined in the CCA and ACL, across Australia and these obligations are enforceable by courts and tribunals in every jurisdiction.

Figure 6. The Australian consumer product safety enforcement framework (89)



Some important terms in the ACL are unfair contract terms or practices, consumer quality guarantees and loss recovery for breaches. Certain provisions in the ACL render unfair terms in standard-form consumer contracts void while others protect against exploitative practices such as bait advertising and pyramid selling schemes. The Commonwealth Government is exploring making the use of unfair contractual terms unlawful and introducing civil penalties for parties taking advantage of these terms (86). It should be noted unfair term provisions do not apply to contracts between businesses. There is also a single approach to product safety across Australia with consumer protection agencies in each jurisdiction tasked with identifying unsafe goods and promoting safe practices through public education. Agencies are also able to issue warnings about product safety, recall or ban products and enforce mandatory safety standards. Safety information about various products has been collated on a single website by the Australian Competition and Consumer Commission (ACCC): www.productsafety.gov.au.

The ACL makes it an offence to engage in misleading or deceptive conduct, unfair practices as well as various other violations of consumer standards and protections. It is a civil offence, and penalties include a fine of up to AU$10 million, three times the benefit obtained from the conduct or 10% of annual turnover for the business. The Court can also issue a non-punitive order forcing the individual or business to provide compensation for their conduct. The affected party or

consumer can seek damages for harm or loss caused to them because of a contravention of the ACL. Individuals and corporations who are convicted of such an offence can also have a criminal conviction recorded in relation to their conduct in addition to fines. Individuals can also be disqualified from managing a business for violations of the ACL.

Multiple consumer agencies are responsible for enforcing the ACL with the peak statutory body being the ACCC. The ACCC is an independent Commonwealth statutory body that is responsible for enforcing the CCA and other legislations that support fair training and competition (90). It consists of a Chair, two Deputy Chairs and four Commissioners. The Commissioners oversee the ACCC's various committees and boards including infrastructure, communications, digital platforms, and consumer data rights. The Digital Platforms Board is currently exploring the market surrounding the supply of internet search engines, social media services, electronic marketplace services and digital advertising services (91). These inquiries are conducted following directions by the Commonwealth Government. Each state and territory also have its consumer agencies that help the ACCC enforce the ACL. Consumer agencies are further supported by a Trans-Tasman regulatory framework answerable to the Council of Australian Governments Legislative and Governance Forum on Consumer Affairs. The Council consists of all Ministers in Australia and New Zealand responsible for consumer affairs. A breakdown of this framework can be found here (89).

A person or business can avoid prosecution by offering a consumer agency an enforceable undertaking that they will comply with consumer laws and protections moving forward (89). This undertaking can be enforced by courts. Consumer agencies can also seek remedies for violations of the ACL without identifying the parties involved. These agencies also release standards and guidelines to support compliance with consumer protections and can issue warnings about possible breaches or failures to comply with consumer protections and guarantees.

Therapeutic Goods Act 1989 (Cth) and associated regulations

The *Therapeutic Goods Act 1989* (Cth) (The Goods Act') determines how medical devices, medicines and other therapeutic goods are imported or exported, manufactured, advertised, and labelled (92). The Goods Act is supported by regulations consisting of the *Therapeutic Goods Regulations 1990* and *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth). Therapeutic goods need to be registered or listed on the Australian Register of Therapeutic Goods before the device can be sold or used in Australia. Therapeutic goods usually belong to three categories: medicines, biologicals (i.e., containing human cells or tissues) and medical devices (93). Medical devices include software that uses the information to provide health services or recommendations to consumers and health professionals. The intended purpose of the therapeutic good determines whether it falls under one of these categories.

The Therapeutic Goods Administration (TGA) is the national regulator for therapeutic goods. It is responsible for assessing goods for their quality, safety, and efficacy (only for high-risk medications e.g., all prescriptions) before they can be registered or listed on the Register. It also monitors the manufacturing of therapeutic goods and regulates product risk before and after goods reach the market. The TGA has been able to secure widespread voluntary compliance with the legislative scheme and operates on a 'benefit of the doubt principle. This principle assumes businesses have the intention to comply with the scheme. Consequently, the TGA seeks to target sectors of the market that are more likely to be non-compliant with preventative actions such as education and audits.

Regulatory responses will be escalated if there is persistent non-compliance, or if the alleged breach has a significant impact on consumer safety. The TGA and consumer agencies can issue warning letters that specify corrective actions to be taken, suspension or recall of therapeutic goods, cancellations from the Register, advertising directions and infringement notices. More serious actions include infringement notices with fines payable to discharge the notice, enforceable undertakings to ensure compliance with regulations or injunctions to compel compliance. Further action can be taken against a business if there is a failure to pay or comply as these actions are commonly reserved for breaches of offences or civil penalty provisions. The TGA can also apply to the Federal Court of Australia seeking civil penalties against a business for an alleged breach. It can also initiate criminal proceedings against the business by submitting an evidence brief to the Commonwealth Director of Public Prosecutions. Criminal penalties include imprisonment terms of 5 to 7 years.

The Act considers telehealth, mHealth applications, wearables, health data and analytics, personal genomics, machine learning, AI, medical software and imaging and EHRs to be medical devices. The full definition of medical devices is listed in section 41BD of The Act. Interestingly, digital mental health tools are excluded from regulations if the software complies with, and references, established clinical practice guidelines in the tool and the user can view these guidelines. Failure to meet these exclusionary criteria will result in the mental health tool being regulated by the TGA.

The TGA uses a four-tier classification system ranging from the lowest at Class I to the highest at Class III with regulatory oversight increasing as the classification increases (see Table 2.3). The manufacturer is responsible for deciding on the appropriate classification based on the intended purpose of the device. Manufacturers include software developers as

defined in The Act. The TGA has developed a classification tool to assist manufacturers in determining the appropriate classification of a medical device here (92). In-depth guidance can be found here (94).

Table 2.3. Classification System for Medical Devices (95)

Risk Level	Classification(s)	Examples
Low	Class I	• Surgical retractors • Tongue depressors
Low to Medium	Class I – supplied sterile Class I – with a measuring function Class IIa	• Sterile surgical gloves • Medicine cup with specific units of measurement • Dental frills; ultrasound machines; digital or infrared thermometers
Medium to High	Class IIb	• Surgical lasers • Diagnostic X-ray
High	Class III	• Prosthetic heart valves • Absorbable surgical sutures • Hip prostheses (for example, replacement of hip joint) • Pacemakers

The manufacturer must first obtain a certification from the TGA for all medical devices except those of Class I classification. Once obtained, sponsors of medical devices must submit the certification to the TGA as evidence of compliance by the manufacturer. Sponsors take legal responsibility for their import to and export from Australia (16). Sponsors must ensure devices are added to the Register before selling the product, the device is correctly classified, and the device is otherwise compliant with other regulations such as advertising and customs requirements. The sponsor must be an Australian resident or incorporated body conducting business in Australia (16).

A sponsor or manufacturer must also show the medical device meets all relevant Essential Principles. These Principles are listed in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. These principles concern health and safety relating to the use, design and construction of medical devices, long-term safety, suitability for intended purposes, and benefit-cost analysis of their use. There is also a focus on the information provided with medical devices, particularly instructions for use. Schedule 1 list provides an extensive list of information that must be made available to the consumer or patient with the device. A checklist of the Essential Principles can be found here (96).

New classification rules have come into effect on 25 February 2021 for software-based medical devices intended for diagnosing or screening for a disease or condition, monitoring the state or progression of a disease or condition, specifying or recommending treatments or providing therapy. These rules determine the relevant classification based on purpose, target audience, risk to the individual or public health and risk of harm. A lower classification may be sought if the information is being provided to a health professional for diagnosis, screening, monitoring, or treatment identification. The health professional must however have relevant expertise or experience in the medical speciality or field for which the device was designed. The TGA has created a table to assist manufacturers and sponsors determine the relevant classification that has been reprinted below in Table 2.4.

Table 2.4 Summary of the new classification rules for software-based medical devices (16)

Summary of the new classification rules for software-based medical devices		
	Diagnosing and/or recommending treatment or intervention for a disease or condition	
	Provides information to an individual	Provides information to a health professional

Risk to the individual or public health	**Death/severe deterioration/high public health risk**	Class III	Class IIb
	Serious disease or condition/otherwise harmful/moderate public health risk	Class IIb	Class IIa
	Any other care	Class IIa	Class I
		Screening and/or specifying a treatment or intervention for a disease or condition	
	Death/severe deterioration/high public health risk	Class III	
	Serious disease or condition/otherwise harmful/moderate public health risk	Class IIb	
	Any other case	Class IIa	
		Monitoring the state/progression of a disease or condition	
	Immediate danger to a person/high public health risk	Class IIb	
	Other danger to a person or another/moderate public health risk	Class IIa	
	Any other case	Class I	
		For providing therapy through the provision of information	
	May result in death/severe deterioration	Class III	
	May cause serious harm	Class IIb	
	May cause harm	Class IIa	
	Any other case	Class I	

Certain medical devices have been completely de-regulated by the TGA under the February regulatory changes while others have been exempted. An exemption means that the TGA retains minimal oversight over the product and the device does not need to be registered. Excluded products include consumer health products that do not provide specific treatment advice such as health and wellness products, coaching software, the patient reported experience and outcome measures and patient surveys as well as digital mental health tools. Likewise, enabling technology such as communication software for telehealth consultations, health administration software, and medical image storage is excluded. EHRs are also excluded if compliant with clinical standards. Medical devices for Clinical Decisions Support are exempt from being included on the Register if they are not intended to directly process or analyse medical images or signals from other devices, are only used to provide or support medical recommendations and are not intended to replace the clinical judgments of health professionals.

Other Statutory Schemes

National Safety and Quality Health Service (NSQHS) Standards

Most health service organisations, including all hospital and public dental practices, have to be accredited to the NSQHS Standards. There are eight standards concerning governance, consumer partnerships, infection control, medications, integrated care, patient and provider communication, blood management and responses to acute deterioration (97). Each standard contains a list of criteria for assessment, explanatory notes, and actions to enable health service organisations to meet these standards. No specific standard exists for digital health technologies but digital health services such as telehealth must meet these Standards. A copy of the standards can be found here (97). All governments determine the organisations that must meet these standards. Any health service organisation can however volunteer to be an accredited practice or service.

The Australian Commission on Safety and Quality in Health Care is responsible for setting these standards and facilitating the accreditation scheme while the relevant Health Ministers endorse the standards. Health service organisations must outline what actions have to be taken to meet the applicable Standards and select an accreditation agency to assess their compliance. A contractual relationship will be created with the agency that will make the assessment data available to government health departments and the Commission for performance review (98). It is also the Commission's responsibility to approve accrediting agencies to facilitate assessments of health service organisations. The Commission is also required to report annually to Health Ministers about safety and quality in healthcare.

The Commission has also established National Safety and Quality Digital Mental Health (NSQDMH) Standards and National Safety and Quality Primary and Community Healthcare Standards. The three NSQDMH Standards are specifically concerned with the quality of digital mental health services to protect users from harm. These standards are **voluntary** and are designed to be delivered at the individual provider level as opposed to organisation-wide for NSQHS (27). However, if an organisation only delivers digital mental health services, then the organisation will also be considered a service provider for the NSQDMH Standards. Digital mental health services include all services provided via a digital platform. It does not include digital technologies that are incidental to the delivery of care such as EMRs or decision-support tools.

More importantly, the Standards were developed in collaboration with the service users, consumers, legal and technical experts, and healthcare professionals. The NSQDMH Standards were finalised through public consultation and pilot assessments against current systems for digital mental health services (99). The first Standard, Clinical and Technical Governance, deals with the safeguards that must be checked to deliver a reliable and safe service such as workforce qualifications and privacy and security of digital systems. The second Standard, Partnering with Consumers, ensures digital mental health services are delivered in collaboration with users such as involving patients in the development of the service. The last Model of Care Standard determines how models of care are to be set up and delivered, harm is to be minimised and how to respond to acute deterioration. A full description, criteria and explanatory notes for these Standards can be found here (100).

Cyber Security

The Commonwealth Government released a Cyber Security Strategy in 2020 dealing with the security of Australians online. It is specifically concerned with preventing criminals, nation-states and state-sponsored actors from accessing sensitive information, especially for financial gain. The Strategy invests AU$1.67 billion over 10 years to invest in infrastructure for better protection online, investigating cybercrime, 24/7 advice hotline for small and medium businesses and families, and increasing cyber resilience and community awareness of cyber security. The Strategy has been designed as a comprehensive response to cyber threats across industries, including Health, where the Australian Cyber Security Centre has recorded over 150 cyber security incidents in the 2019-20 financial year. Health services using digital technologies are prioritised in the strategy due to the vulnerability of service users and the essential nature of these services. The full strategy can be found here (101).

Consumer Data Right

The Commonwealth Government has also introduced a Consumer Data Right to give consumers more control over their information. This Right enables consumers to request data about products or data that relates to them. It also outlines processes concerning data privacy including deletion, de-identification and transfer of data. Its application is currently limited to the banking sector with plans to introduce it to the energy sector. The Right is legislated in the *Competition and Consumer (Consumer Data Rights) Rules 2020*.

4. DIGITAL HEALTH TRENDS

Australian Digital Health Market

Australia is a highly digital society with the majority of Australians being digitally connected in some way (5, 102). By the end of 2018, there were 14.7 million internet subscribers in Australia, and 91% of the population have a smartphone (5). The majority of Australians have used the internet to research health issues, including 69% of older Australians (over 65 years of age) (5). However, only a very small minority of Australians (6%) find sources of health information online they trust (5).

Not only is the Australian population digitally savvy, but Australia has a long history of harnessing digital technologies to improve healthcare delivery (5, 20). Australia has had a decades-long policy of supporting innovation (20). Coupled with this the nation has made a considerable investment in building health infrastructure (1) and developing digital health capabilities (20). In 2018 Australia's Digital Health Trade and Investment Commission argued that digital health is ubiquitous and cuts across every part of the health ecosystem from prevention to diagnostics, to treatment to management and research (103). Despite this Australia has been slow to adopt digital health compared to other similar health systems, with medium-low level digital intensity reported in the health sector (102).

Software as a Medical Device

In Australia there has been a significant increase in SaMD over time (104). There has been an increase in SaMD's registered in Australia that was made domestically, which is different from other registered medical devices which are predominantly developed overseas. The breakdown of SaMDs that have been approved for use in the Australian market is as follows:

- Class I – 51%
- Class II – 32% (Class IIA)
- Class III – 2%

Examples of digital health technologies that are regulated as SaMD by the TGA include Hearing Loss Diagnosis (Class I: Low Risk); Goniometer (Class Im: Low-Medium risk); ECG app (Class IIa: Low-Medium risk); ICU breathing monitor (Class IIb: Medium-high risk); and Melanoma diagnosis to consumers (Class III: High risk) (105).

Software and apps that meet the TGA's definition of being a SaMD are regulated before they can enter the Australian market (16). The TGA considers regulation for many different types of SaMD including 1) software on general computing platforms such as smartphones, tablets and online; 2) Software that is part of a medical device (regulated as part of that device); 3) Apps that control a medical device (regulated as an accessory or a device) and 4) Apps that rely on medical device hardware such as sensors in addition to a computing platform (105).

Australia, like many nations around the world, faces several challenges with SaMD technology. A widely recognised challenge is that digital health technologies often have different levels of regulatory oversite (20). This is because these technologies have varied risk profiles, and the risk profile may be different for different individuals (15, 106). Challenges facing regulators include the risk of poor performance for software, which is greater for physical devices as the software doesn't generally undergo clinical testing in the way physical devices do; there is less literature on clinical validations; and people use the software in unexpected ways which makes determining safety difficult (105). In Australia, there are some examples of SaMD being recalled, and there have been instances of adverse events being reported (104). Although SaMD adverse events have low injury levels associated with them, there have been a large number of reports indicated as 'unknown' suggesting ascertaining the exact level of injury from SaMD can be difficult (104).

Consumer Digital Health

In the Australian context, as is the case in many regions, consumer digital health encompasses a breadth of diverse technologies. These technologies include apps and self-monitoring wearable devices, fitness platforms, online search engines, blogs and medical websites, health-related games, social media, and online communities for patient and career support (19). Digital health industry is heavily focused on developing technologies aimed at consumers for home use, self-management and behaviour change, chronic conditions and mental health (20). Consultations with Australians have indicated that many individuals in the community are willing to use technologies to support their health and well-being or to share their health data with providers (1, 107).

This finding aligns with a recent 2016 survey of 500 Australians on their technology use. Over half owned a wearable device of some kind, with health being the number one reason stated for buying the device. Of the group of respondents

who had a wearable 48% of respondents indicated owning a fitness band and 34% a smartwatch (108). This survey further aligns with data from a 2021 survey of 2,000 Australians aged 18 – 75 which indicated that 58% of respondents used a smartphone or smartwatch to monitor their health, up from 28% in 2019 (109). When it comes to apps, the average Australian has over 100 on their smartphone, and Australians are likely purchasing and downloading an increasing number of health and fitness apps, in line with global trends (110). When using smartphone apps to monitor health and well-being Australians are often using them to monitor their daily activity in the form of step counts, heart rate monitoring and monitoring sleep patterns (91).

Many consumer health technologies fit within one of the five categories the TGA excludes from regulation (105). This includes the category 'Consumer Health Products', which describes devices used by the community for prevention, management and follow-up that do not provide specific treatment or treatment suggestions and may include technologies that fit within the excluded category 'Digital Mental Health Tools'.

The breadth of consumer digital health technologies is a challenge in Australia. A major concern is that many of these technologies have little evidence they provide health benefits, and many are not evaluated in any way (19). Although not always the case, many of these consumer technologies do not require clinical evidence to demonstrate they are effective or require regulatory oversite (20). An additional challenge created by consumer digital health is that these technologies often generate a considerable amount of data about the user that is not always encrypted when it is transmitted. This can make consumer data vulnerable to privacy breaches or it may be co-opted for marketing purposes (19).

Health Information Technology

Australia has made a significant investment in infrastructure and systems to support digital health development (19), particularly in the context of Health Information Technologies. This investment is a key enabler for the growth of Australia's digital health industry as it provides a unique opportunity to leverage key infrastructure for innovation (20). Further, it is anticipated that investment in key infrastructure will enable further improvements in Australia's health system by guiding health service planning, policy and research (5).

There are several Health Information Technologies that fit within one of the five categories the TGA exempts from regulation (105). These categories include 'Analytics' technologies that are population-based; 'Enabling Technologies' such as those that enable medication dispensing; 'Laboratory Information Management Systems'; and 'Digitisation of Analogue Systems' describing technologies that digitise paper-based or other published clinical rules or data including simple calculations and EMRs.

Although Australia has focused heavily on the implementation of technologies that enable the collection and use of electronic health information, the digital health landscape still has challenges to overcome. A major challenge facing Australia is successfully accessing siloed health data, which has remained a problem despite current infrastructure investments (19). As with many other digital health technologies, ensuring privacy and security is a challenge for many information systems which is a noted concern for Australian consumers (107). The development of infrastructure that can safely and securely store and share electronic health data has also been noted, particularly in the context of developing state and territory-wide EMRs (111).

National Electronic Health Record

A key infrastructure investment has been the development of a national EHR, My Health Record (111). Development of My Health Record began in July 2012, and as of 2019, the information technology had reached 90% of health system users in Australia (5). My Health Record is a secure place to keep key health information so that it is available to individual Australians and their healthcare providers whenever it's needed, including in an emergency (112). It contains key health information like immunisation history, pathology and diagnostic imaging reports, prescription and dispensing information, and hospital discharge summaries (113). As of May 2022, there were 23.3 million My Health Records in Australia, and 22 million had data in them (114). This included 217,000 people registering for My Health Record who had previously opted out of the system.

Electronic Medical Records

In addition to the national EHR, many Australian healthcare organisations also use EMRs. Using an EMR is increasingly becoming part of a health professional's daily work across healthcare settings in Australia (115). The systems used in Australia were largely developed by vendors in the United States and adapted for the Australian context (115). EMRs generally include core functionality such as the ability to document patient history, notes and treatment plans (115). A

number of states and territories in Australia have implemented or are in the process of implementing some form of state-wide EMR in public hospitals including NSW (116), Queensland (117) and the ACT (118).

The widespread uptake of EMRs in a range of healthcare settings in Australia, and globally, has provided an opportunity to implement integrated Clinical Decision Support Systems into this infrastructure (119). Clinical Decision Support Systems are pieces of software that help prompt clinicians to follow best practices and support the delivery of evidence-based care (119). The extent to which Clinical Decision Support Systems have been implemented in Australia is difficult to gauge, but there are examples of them being used in both rural and metropolitan contexts (120).

Electronic Prescribing

Electronic Prescribing was introduced in the 2018-2019 Budget Statement, as a Department of Health Budget Measure (121). Subsequently, the Australian Government changed legislation to make electronic prescribing of medicines on the PBS legal (122). Electronic prescribing describes the use of a digital prescription instead of a paper-based document (123). It is considered important as part of the Australian health landscape for multiple reasons, but particularly because it supports digital services such as telehealth to be delivered in a way that supports continuity of patient care (124).

In addition to Electronic Prescribing, pharmacists in Australia have access to several other digitally enabled innovations that improve the collection and exchange of electronic health data. This includes the ability to upload and exchange dispensed script data through a number of services (125, 126). The first of these services, the prescription exchange service, has been available since 2009 (127). Coupled with this, Australia has a national real-time prescription monitoring system that uses prescribing data from dispensing software to monitor controlled medicines with the aim of minimising misuse of pharmaceuticals (128).

For prescribers and pharmacists to use Electronic Prescribing they must have access to special software that can create a unique token in the form of a QR code which is then emailed to the patient or sent via SMS to their mobile phone (129). The QR code unlocks a key that allows pharmacists to unlock the electronic prescription and dispense it (129). There is also a digital solution, Active Script List (ASL), which manages tokens in a single spot for patients that have a large number of prescriptions to manage (129). Since May 2020, more than 55 million electronic prescriptions have been issued by 41,000 eligible prescribers (123).

Communication Technology

As with consumer digital health, health communication technologies describe a broad category of technologies that can enable real and non-real-time interaction between different stakeholders in the health sector. In Australia, the most common examples of health communication technologies are Telehealth and Virtual Care, which are described in the sections below.

Health communication technologies are generally excluded from regulation by the TGA (105). This is because many of them will fit into one of the five categories of technologies excluded from regulation. Specifically, the category 'Enabling Technologies' describes technologies that enable telehealth, remote diagnosis, healthcare or dispensing.

A key challenge facing Australia in the adoption of digital health communication technologies is connectivity, with many individuals unable to connect to reliable, accessible and affordable infrastructure (130). This is a particular challenge in rural and remote areas where access to reliable high-speed internet services can be hard to obtain (131). Coupled with this, there is a need to overcome interoperability challenges across digital health systems that are currently preventing the implementation of digitally enabled models of care that would improve access to high-quality and affordable care (132).

Telehealth

In Australia, Telehealth can be used by health professionals to consult with patients remotely, either via phone or video service (133). A wide range of health professionals can use Telehealth as part of care delivery and receive reimbursement from the Australian government, including medical practitioners, nurse practitioners, midwives, practice nurses and Aboriginal Health workers (18). Between March 2022 and June 2022, 110.4 million telehealth services were delivered to 17.6 million patients, by approximately 94,144 practitioners (134). Prior to the COVID-19 pandemic, telehealth consults represented less than 1% of consultations billed through Medicare and now, post-pandemic, have ballooned to more than 25% of all consultations (1).

Virtual Care

Interest in the delivery of Virtual Care is growing in the Australian digital health landscape, partially accelerated by the COVID-19 pandemic. In the Australian context, Virtual Care describes non-face-to-face clinical care, professionally enabled through digital mechanisms (1). A major survey of the Australian community in 2021 found that over 70% of Australians are willing and ready to use Virtual Health (135).

A key enabler of Virtual Care is the development of Virtual Hospitals and Digital Hospitals such as Royal Prince Alfred (RPA) Virtual in Sydney, Australia (136) and Princess Alexandra Hospital in Brisbane, Queensland (137). Virtual Hospital initiatives are designed to offer personalised services to the community by using technology to remotely connect patients and carers with health professionals whenever needed (138). In some Australian jurisdictions government agencies are also working collaboratively to establish initiatives to increase the capacity for Virtual Care in the Australian health system (139, 140). This includes bringing together key stakeholders to share ideas and strategies in the area of virtual care, and to disseminate guidelines to support the health workforce in delivering care virtually (139).

Impact of COVID-19 on Digital Health

The World Health Organisation declared the novel coronavirus a global pandemic on March 11th, 2020 (141). In Australia, like in many countries, this declaration had a major impact on the health landscape. On March 18th March 2020, the Australian Governor-General declared that a human biosecurity emergency exists. The declaration gives expansive powers to the federal Minister for Health to issue directions and requirements to combat the emergency (142).

Concurrently, the Australian Government introduced significant restrictions and lockdowns that limited the movements of the Australian population, which were to be implemented by the individual state and territory governments (143). By the end of March 2020, the Australian borders were closed, and the majority of the population was in a state of lockdown (143). This meant people could only leave their homes for essential reasons such as exercise, and groceries, to provide medical care or work and education that could not be provided remotely. There were also severe restrictions on the number of people that could gather in groups outside, and minimum distances people had to be from people outside their household when they interacted with them.

For the Australian health sector, the response to the COVID-19 pandemic had a significant impact. One major change was that there was a need to use technology to support remote delivery of care to the community, which resulted in a widespread increase in interest in digital health. As the adoption of digital health in the Australian health sector was part of an emergency response, it was implemented reactively as required, rather than in a systematic manner. Some of the key areas where the health sector was impacted by digital health is described below.

It must be noted that although the Australian health sector rapidly responded to the COVID-19 pandemic with the adoption of some digital health technologies, the extent to which these technologies will be sustained is unknown. Coupled with this, the adoption of different types of digital health technologies was particularly uneven, with a major focus on areas like Telehealth and Virtual Care.

Impact by technology category

Consumer digital health

In response to the COVID-19 pandemic, there are many examples of Australians using digital technologies to stay connected, active and maintain fitness. A 2021 survey of 2000 Australians aged 18 – 75 years found the number of individuals using smartphones, smartwatches or fitness bands to monitor their fitness had increased significantly compared to data from pre-pandemic surveys (109). Smartphone apps, online resources and video games were used by Australians to stay active and engage in exercise and yoga during the pandemic (144, 145). Digital health was also reported to be used during the pandemic to support mental health, well-being and meditation (109, 145).

To support the public health response to the COVID-19 pandemic, the Australian federal government launched the COVIDSafe App on April 26th, 2020 (146). COVIDSafe is available as a smartphone app and is designed to help identify people exposed to COVID-19 by augmenting manual processes in Australian states and territories (147). In the first month after the COVIDSafe was launched, there were 6,061,686 downloads of the app, and as of May 2021, there were 7,418,328 (146). As of November 15th, 2020, data from the COVIDSafe app had been used to identify 2,579 close contacts from more than 35,939 encounters (146). Registration and use of the COVIDSafe app is voluntary (146)

and Australians who have downloaded the app will receive an alert to delete it from their phones when the Commonwealth Minister for Health declares the COVID-19 pandemic is over (147). In addition to the COVIDSafe app developed by the federal government, a number of states and territories in Australia developed and implemented their own contact tracing solutions utilising smartphones (148-150) as the technology is widely available in Australia (5).

Health Information Technology

Image-based Prescribing

In response to the COVID-19 pandemic, the Australian Government introduced image-based prescribing arrangements into the community health and hospital setting (129). Although electronic prescriptions were available in Australia prior to the COVID-19 pandemic, they were not widely adopted. This was a challenge when Australians were encouraged and/or mandated to stay in their homes in response to the pandemic, as there was no way for prescribers to provide their patients with a prescription that was valid for use by a community pharmacist. Patients confined to their homes with COVID-19 who had paper prescriptions or repeat prescriptions could not transfer these into a digital form for the purpose of dispensing and had to get someone to go to a pharmacy on their behalf to pick up required medications (129).

Image-based prescribing is an alternative to paper or electronic prescriptions, as it enables prescribers to take a photographic copy of the entire prescription and send it to a pharmacy by text message, fax or email. The photograph has to be a clear copy of the entire prescription and ideally include the prescription barcode. The pharmacy could dispense the prescription using this image, without requiring a paper or electronic script. The pharmacist could still claim reimbursement for the prescription on the PBS, as they would for a paper or electronic prescription (129). The prescriber remained legally required to keep a copy of the paper prescription they wrote for a two-year period for audit purposes (129).

As of March 31st, 2022, image-based prescribing could no longer be used in the community health setting but could still be used in hospitals for dispensing by hospital pharmacies (129). After this date, pharmacists could no longer make a PBS claim for image-based prescriptions and required a copy of a paper prescription or an electronic prescription to be sent to them to make a reimbursement claim (129, 230). Image-based prescriptions that were dispensed in the community setting prior to March 31st, 2022, but still had ongoing repeats, could be dispensed after this date, until all repeats had been completed (129).

Communication Technology

Telehealth Services

On March 13th, 2020, the Australian Government introduced temporary MBS items, in response to the COVID-19 pandemic (151). These MBS items augmented the existing Video Consultation items already listed on the MBS (152). These existing MBS items for Telehealth consults were not widely adopted by many health professionals. Some fields did have relatively widespread use of the items for delivering care remotely, such as areas of allied health like speech pathology (141), physiotherapy (153) and exercise physiology (154). One reason that these MBS items may have not been widely adopted is the requirement that to claim them, the patient and specialist were required to be located a minimum of 15km apart at the time of consultation (152).

The temporary MBS Telehealth items officially ended on the 31st of December 2021, but as of January 1st, 2022, some of the temporary items have transitioned to on-going ones (151). The temporary MBS items were designed to be for out-of-hospital services, with the specific intent of making services available to help reduce the risk of community transmission of COVID-19 and protect both patients and healthcare providers (151). The temporary MBS items were available to General Practitioners (GPs), medical practitioners, specialists, consult physicians, nurse practitioners, participating midwives, allied health providers and dental practitioners in the practice of oral or maxillofacial surgery (151). Prior to the pandemic, it was notably uncommon for GPs to provide Telehealth consults, but this changed dramatically as a result of the COVID-19 pandemic (155). There was such widespread adoption by GPs that the Royal Australasian College of General Practitioners (RACGP) published specific resources for their members on the delivery of Telehealth (155). Interestingly, there was a notable tendency for GPs to deliver virtual consults via telephone during the pandemic, instead of using video consults (156).

Another significant impact the COVID-19 pandemic had on Telehealth was that a number of large private health insurance companies introduced options for customers to claim virtual consults for some health services (157-159). In Australia, the

health system includes both public and private service provision (160). Australians can receive care subsidised through Medicare from public providers through a large network of hospitals, primary care networks and other healthcare organisations. In addition to this, Australians have the option to pay for private health insurance, which allows them to choose to receive care from a large network of private hospitals and other healthcare providers. This care can also be provided to individuals as private patients through the public system. Healthcare delivered to individuals by either of these two privately covered options is reimbursed through private health insurers, and generally, patients who do not have private health insurance do not access care through private healthcare providers. Private health insurers had specific criteria for their members about when a service delivered via Telehealth could and could not be covered via private insurance (157-159). Many private health insurers also only offered Telehealth items for members for a set period, commonly until 31 December 2021 (157-159).

Virtual Care

To respond to an increasing need for health services in Sydney, RPA Virtual was launched in early 2020 as an alternative and sustainable model for delivering care remotely. RPA Virtual care centre is designed to offer personalised service for the community, by using technology to connect patients and carers with health professionals 24 hours a day, 7 days a week (138). The virtual hospital is situated within RPA Hospital, a major metropolitan hospital in Sydney, Australia within the Sydney Local Health District.

Between the launch in February 2020 and July 2021, RPA Virtual had provided remote care to more than 13,000 patients (161). Whilst RPA Virtual was not intended to support the pandemic response, the timing of its launch made it invaluable to the pandemic response. As of April 2021, the Virtual Hospital had supported the provision of care to 11,584 unique patients with COVID-19, both remotely in the community and patients in health hotel quarantine in NSW (162). In addition to supporting the pandemic response in 2020 and 2021, RPA Virtual delivered medication support and symptom monitoring, as well as a virtual fracture clinic (161). The Virtual Hospital currently supports a range of continuing models of care including but not limited to supporting COVID-19 Clinical Care Patients, Medication Monitoring, a Virtual Fracture Clinic, Digital Literacy Support, RACF Triage Line, Aboriginal Chronic Care post-discharge follow-up and Chronic and Complex Care. Moving forward the Virtual Hospital is seeking to support the delivery of New Models of Care in areas including but not limited to Virtual Rehabilitation, Low Back Pain, Long COVID, Trauma Follow-Up, Aboriginal Care Navigators and Psychology Brief Intervention. Delivery of care through RPA Virtual continues to expand and it has plans to implement new programs and care delivery programs in the future.

There was considerable interest in enabling Virtual Care delivery by the Australian health system in response to the COVID-19 pandemic. To achieve this in NSW, the State Ministry of Health established clinical communities of practice to support the state's response to COVID-19, one of which focused on Virtual Care (139). The Virtual Care Community of Practice was convened by the NSW Agency for Clinical Innovation (ACI) (140). The Community of Practice was established to provide an opportunity for sharing ideas, strategies, local solutions, and concerns with respect to COVID-19 pandemic preparedness. Additionally, the Virtual Care community of practice published a large number of guides to support the health workforce in delivery care virtually during the pandemic (139).

Other examples of NSW Health virtual services of interest are the Virtual Rural Generalist which provides virtual medical care to small under-served rural communities, and the Telestroke service which provides support for early intervention for patients with stroke outside of metropolitan areas.

System level impact

Workforce Capabilities

The COVID-19 pandemic acted as an accelerator for many areas of digital health in Australia, many of which were already being explored but at a much slower pace. One major area that came under the spotlight because of the COVID-19 pandemic was health workforce capabilities using digital technologies to support health, well-being, and health services delivery. Several government agencies and peak bodies published guidelines and frameworks for understanding the skills and knowledge the health workforce required to use health technology safely and effectively. Key publications included the ADHA's 'National Digital Health Workforce and Education Roadmap' (2021) (23); The AMC's 'Capability Framework in Digital Health in Medicine' (2021) (163) and the 'Australian Institute of Digital Health' (AIDH) 'Australian Health Informatics Competency Framework' (2022) (164). Although these publications were released after the COVID-19 pandemic was declared, it should be noted that some had been identified as priorities prior to the pandemic.

In addition to more generalised workforce capabilities guidelines, many organisations focused on developing technology and/or service-specific guidelines to help with the rapid adoption of digital technology by the health workforce during the pandemic. Examples of this include The Australian Health Practitioner Regulation Agency's (AHPRA) 'Telehealth guidance for practitioners' (165); Allied Health Professionals Australia's 'Telehealth Guide for allied health professionals (166); and the RACGP's 'General Practice Telehealth Resources' (155).

Funding Schemes

The Australian Government made a considerable investment in COVID-19 research during the pandemic, which provided potential opportunities to support digital health research. The primary mechanism for funding this research was through the Medical Research Future Fund (MRFF) scheme (167). The MRFF is an ongoing research fund set up by the Australian Government in 2015. As of 2020, the fund totalled AU$20 billion. The fund is designed so that the Government can use it to invest in medical research initiatives agilely, which made it particularly useful in response to the pandemic. The MRFF has funded multiple schemes in response to the pandemic that could support digital health research including the 2020 COVID-19 Mental Health Research Grant Opportunity, the 2020 Rapid Response digital health Infrastructure grant, and the 2021 COVID-19 Treatment Access and Public Health Activities Grant Opportunity (168).

Other state schemes to support funding for COVID-19 digital health research and development were rolled out by individual states and territories. For example, the NSW Government released COVID-19 Research Grants in 2020 which were designed to fund project areas in priority areas and directly support the NSW Health response to the pandemic (169). The grants were released in two rounds, both of which had topics that could support research into digital health development and implementation in health services. The first round was focused on 1) Diagnostics research; 2) Prevention of infection; 3) Treatment, including antivirals and immunosuppressive agents; and 4) Public and Population Health. In round two grants were requested for topics including 1) Identifying effective models of care; 2) the Mental health impact of COVID-19; 3) Public health messaging; 4) Prevention and therapeutics and 5: Diagnostics.

Although the government released some additional funding schemes that could be used to support digital health innovation, industry groups reported finding it challenging to access government funds or raise other capital because of the pandemic (20). A lack of digital health specific grant programs has also been reported as hampering Australian innovation in this space (20).

Market Opportunities

Virtual and Home-based Care

During the COVID-19 Pandemic Australia made a significant investment in technologies that enabled Virtual Care. This included initiatives to reduce the number of patients that needed to be treated in hospitals by using technology to triage and deliver care (136). It also includes the use of technology so patients can manage their care in the home, or in places that work best for their needs. Aligned with this, we know the Australian digital health industry is heavily focused on developing technologies for use in the non-clinical setting, including the home, the workplace and aged-care settings (20). This trend indicates there is likely to be an increasing number of technologies for supporting Virtual and Home-based care in the future, proving new market opportunities for virtual care.

In the last two years, Australia has seen rapid adoption of Telehealth outside the specialist setting (134, 135). There is also evidence of commercial entities developing novel approaches for developing Telehealth services in Australia (170). Given this market growth, it seems likely the trend towards Telehealth will continue in Australia into the future.

Accessible Health Data

Improving the collection, extraction and use of health data is a recognised policy focus of the Australian digital health landscape (14, 25, 51). As the Australian digital health landscape this focus on data use is likely to become increasingly prevalent, in part because digital technologies enable the widespread collection of data about every aspect of people's lives. It has been noted that increasingly policymakers will have to focus on responding to technology transfers: the process of moving technology from a person or organization from the person who owns it to another person/organization to realise new benefits from it (105). Aligned with this, there is likely to be an increase in new entrants in the digital health area who have not traditionally worked in healthcare, leading to digital disruption (102).

Currently, we know that the Australian population has an interest in the use of health data, with a recent survey finding 80% of respondents were ready to share their health data in a digitally enabled health system (1). Increasingly there is an expectation of and interest from consumers in being in control of their health data (1). Aligned with this, there is a growing need to have a digital health data system that is interoperable and allows all relevant parties, including consumers, access to data (19) (See Table 2.2). Digital health data systems, particularly health records, will also need to be more user-friendly and work better than they currently do in future (19).

Precision and Predictive Health

Digital technologies, particularly those that leverage AI, are enabling a new era of precision and even predictive medicine. This trend is likely to increase in the future, both, in Australia and globally. The TGA has identified Machine Learning and AI as emerging areas of focus for regulators in future, along with diagnostic tests that use software (105).

In Australia, there is a significant market opportunity to harness AI more widely in future, due to the data-rich nature of the health system (171). Australia does not currently have widespread adoption of AI in routine practice in the health system. To realise the market opportunity of AI Australia needs to establish the technical, regulatory and societal infrastructure to enable the safe implementation and use of this technology in health care (171). If this market opportunity can be realised there is huge potential for precision health to be adopted in Australia (171). The benefits of precision health include providing targeted treatments for major interventions, supporting the early diagnosis of disease, mapping out treatment guidance for clinicians and supporting clinicians' and patients' tailored solutions to health problems (172).

Equitable Digital Health

In Australia, there is growing recognition that health technologies have created equity challenges in the population who already had access barriers to healthcare (1). These challenges are likely to continue in the market in future unless actions are taken to address them. Ethical and social issues that need to be considered when growing the digital health market in Australia include whether some individuals or social groups might be stigmatised, particularly with an increasing focus on self-management of health (19). A focus needs to be placed on raising awareness of the risks and benefits of sharing health information, particularly for people of lower educational attainment (107). There is an opportunity to innovate on solutions aimed at increasing digital health literacy in populations where there is discomfort using digital health technologies, and low awareness of how digital health technologies can support individual healthcare (1). Another opportunity for innovation in future is the development of infrastructure and digital health solutions that enable full participation of consumers currently excluded from the space due to health status, lack of skills or because their needs are not adequately realised (19).

Digital Health Capable Workforce

Australia has increasingly realised the need to build a digital health capable workforce, as recognised in a number of digital health and workforce capability-specific strategies (23, 172). This trend is likely to continue in future. It has been noted that digital health capabilities currently cluster in specific areas. In future, there will likely be market opportunities to develop workforce capability frameworks for health professions currently under-supported such as allied health (173). There will also likely be an increasing demand for universities and other education providers to develop agile training solutions, such as micro-credentials, that can respond to evolving skills and knowledge needs of the health workforce (174). Some Universities such as the University of Sydney have commenced integrating knowledge of digital health as part of the core curriculum in health programs like medicine including experience in virtual health care.

5. DIGITAL LITERACY IN AUSTRALIA

Digital literacy among decision-makers, healthcare providers, and the public

Digital technologies can be a barrier to accessing healthcare if people do not have the knowledge or skills to use digital devices or platforms. This barrier can be addressed by improving digital literacy. Digital literacy refers to the skills and competencies needed to use digital technologies to support patient care, medical education and training, informed decision-making, and other health-related tasks. These skills and competencies include the ability to search, navigate, communicate, and collaborate safely using digital devices (175). It also covers the ability to adapt to new ways of using technologies and critically analysing information sources on/off-line (175). Less than 40% of Australians feel confident that they can safely navigate technological changes (176).

Digital health or e-health literacy references the same ability to search, navigate and use digital devices to address health problems or understand health information (177, 178). Interestingly, the Australian Commission on Safety and Quality in Health Care divides health literacy into individual health literacy, as defined above, and the health literacy environment. The environment refers to "the infrastructure, policies, processes, materials, people and relationships that make up the health system and have an impact on the way in which people" (179) understand health information and address their health problems. As a result, digital health literacy is a skill that has become particularly relevant in Australia as healthcare systems are increasingly digitised and personal health information is stored on digital platforms such as My Health Record. Likewise, healthcare professionals must possess digital health literacy, often referred to as digital health capabilities, to implement new services and technologies. Inadequacies in these skills will compromise the quality of digital health information and patient safety as digital tools are incorrectly used in care and health promotion (180). Deficiencies will also limit consumer access to health information as patients cannot effectively navigate digital health Services (26).

The Digital Divide

The benefits of digital health ecosystems cannot be realised without improving the accessibility and affordability of digital technologies. Many digital technologies currently being implemented in healthcare, such as telehealth and remote patient monitoring, rely on synchronous communication with patients and/or their devices. This is concerning as access to technology is not equal with almost a quarter of Australians being limited internet users or offline (176). A set of factors, otherwise known as social determinants of health, consisting of age, socioeconomic status, language, and location contribute to this digital divide. Mobile connectivity is only available across a third of Australia's total land area disproportionately affecting internet access for rural and/or remote towns (176). Likewise, half of the low-income households struggle to pay for internet access and are more likely to be limited to one device: smartphones (176). These social determinants of health must be considered before implementing digitally enabled models of care. Otherwise, digital health technologies will likely perpetuate existing patterns of health-related vulnerabilities and inequalities among disadvantaged groups.

The Good Things Foundation Australia, a social change charity, conducted virtual roundtables with consumers, practitioners, academics, and policymakers to determine how the digital health divide could be closed. The first roundtable focused on policy interventions while the second roundtable focused on digital health technologies.(181).

Recommendations from the roundtables for policy interventions include (182):

- Long-term digital health support in the community led by community organisations.
- Building consumer and clinician confidence to use digital health technologies.
- Establishing digital health navigators to mentor clinicians and consumers when using digital health interventions in the community. These navigators would serve as the bridge between consumers and clinicians and help tailor treatment or health information to the needs of the patient.
- Developing a clear framework to improve digital health literacy among relevant stakeholders.
- Improving digital health access for patients across locations, settings, and sub-specialties. There is a particular focus on linking digital health upskilling to professional development requirements and improving funding for care providers.

Recommendations from the roundtables to encourage the sustained use of digital health technologies, specifically telehealth, are (183):

- Targeted educational support to develop skills and confidence to use digital health technologies.
- Equitable access to digital health services by targeting social determinants of health.
- Digital upskilling for clinicians to provide quality and safe care through digital health technologies.
- Streamlining e-prescriptions direct to the pharmacy as opposed to relying on patients.
- Permanent option for face-to-face care and paper prescriptions.
- Investments in ICT Infrastructure for clinicians.

Measuring Digital Health literacy

There is no standardised measure of digital (health) literacy across Australian jurisdictions nor is there a single measure endorsed by any jurisdiction. The Commonwealth government has previously used the Health Literacy Questionnaire, developed by Osborne and colleagues in 2013 (184) to measure health literacy in an Australia-wide census. The census found the majority of respondents agreed that they have sufficient evidence to manage their health and are supported by their healthcare team. The Australian Commission on Safety and Quality in Health Care has collated a list of measures used in Australia to assess health literacy here (pgs. 22-23) (179).

Australian Digital Inclusion Index (185)

Telstra, Melbourne universities and social research organisations collaborate annually to release a report on the Australian Digital Inclusion Index (ADII). The ADII measures the level of digital inclusion among the Australian population. It is administered annually to a representative sample of the Australian population.

The ADII is a composite of multiple indicators across the three dimensions of access, affordability, and digital ability with the final score ranging from 0 to 100. Each dimension covers multiple variables "relating to internet products, services,

and activities". See Table 4.1 for the definition of each dimension. A hypothetical comparator of perfect digital inclusion is used to determine the comparative level of internet access, digital ability, ownership of internet products, personal attitudes, and demographics.

Table 4.1. Definition and Components of the Three Dimensions of Digital Inclusion

Access	**Affordability**	**Digital Ability**
Measures		
Type and frequency of digital connections and device use	The ratio of household income to cost of quality service with reliable connectivity	**Internet Skills Scale** (Deursen et al, 2014) as modified by the ADII team.
Components		
• **Frequency and intensity of use:** ranging from no use to daily use • **Connection type:** fixed broadband or mobile-only • Data allowance and speed • **Types of devices:** desktops, laptops, smartphones, tablets and other smart home devices.	• **Fast internet service** including cable service, NBN 50 or above, or 5G wireless service • Unlimited monthly data allowance through fixed service • Mobile phone data allowance above 61GB per month The Affordability stress score identifies when internet services become less affordable for families. The stress score has four categories: • <2% of household income • 2-5% of household income • 5-10% of household income • >10% of household income A family spending more than 5% of their household income would have to start compromising on other essential household items to maintain a quality service.	• **Basic operational:** downloading and opening files, connecting to the internet and setting passwords. • **Advanced operational:** saving to the cloud, safe downloading, customising devices and adjusting privacy settings • **Information Navigation:** searching, verifying trustworthy information, and managing third-party data collection • **Social:** deciding what and how to share information, communicate online and monitor contacts • **Creative:** content generation and management, broad understanding of applicable rules to content production • **Automation:** connection and operating smart devices and Internet of Things technologies
ADII Dimension Scores (2020-21 period)		
▪ Increase by 0.6 points from 69.4 to 70 in 2021.	▪ 14% of all Australians need to pay more than 10% of their household income to gain quality internet service.	▪ Slight increase of 0.8 points to 64.4 points in 2021.

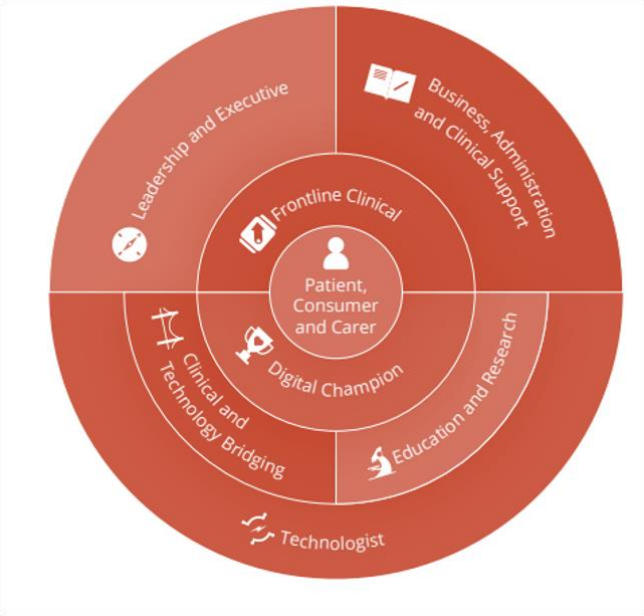
▪ Mobile-only users have the lowest score at 43.4 points.	▪ This is highest among the lowest income quintile in Australia (67%).	▪ Basic operational skills have fallen by 0.4 points.

The ADII has increased yearly with a 3.6-point increase from 67.5 points in 2020 to 71.1 points in 2021. This positive trend is consistent across all jurisdictions, but there is a significant gap of 3.6 between metropolitan (71.1) and regional areas (67.4). The percentage of excluded Australians (ADII score of 61 points or less) has decreased but remains significant at 28% of the national population. This is particularly concerning as these Australians are more likely to have an incomplete secondary education, disability, and lower relative income. The ADII research team recommends that Digital Ability can be improved and maintained through the incidental use of digital internal-enabled technologies in work, education, and recreation.

Workforce Capabilities

Multiple jurisdictions have developed workforce capabilities frameworks to set expectations for digital literacy skills among the health workforces. The ADHA has developed the Digital Profiles Framework for implementation at a national level. The Framework is stratified by the health profession to determine the 'digital profile', or skillset needed for the individual to successfully engage with digital technologies. Figure 7 shows the interactions between the eight digital profiles.

Figure 7 Digital Profiles (23)



These eight profiles are designed to be broad and expand on other frameworks and standards for the adoption of digital health. Each profile contains a set of statements describing the role and expectations of a digitally literate workforce. Multiple profiles apply to the same staff member as demonstrated by the ADHA exemplars, accessible here (page 53)(23). These profiles also serve as a reference point when designing programs to improve workforce digital literacy.

A similar expectation-based framework has been developed by NSW Health in collaboration with the University of Sydney. The eHealth Capability Framework outlines the basic skills and knowledge health professionals need to navigate the digital health landscape. It set expectations of entry-level experience for clinical staff through its four domains of digital technologies, systems and policies, integration of digital health into practice, data analysis and knowledge creation and technology implementation and co-design. Similar to the Digital Profiles Framework, this Framework is also designed to serve as a reference point for the development of education programs to enhance workforce literacy.

The AIDH has also developed a health informatics competency framework in collaboration with academics and professionals. The AIDH is the leading representative body for health informatics and digital health practitioners. Health informatics refers to the leveraging of information and communication technologies for health promotion (164). There are

six domains of expertise covered by the framework: core health informatics principles, leadership and management, information technology, health sciences, social and behavioural sciences, and information science.

Non-Health Specific Digital Frameworks

The Australian Government has secured a nationwide licence for the Skills Framework for the Information Age (SFIA). SFIA is an international standard developed in the United Kingdom for digital skills. It is used by government and private organisations for workforce recruitment, planning and skills assessment for digital professions. It is currently free for use in Australia (186).

What measures are taken to improve digital literacy?

The Australian Government has developed a Digital Literacy Skills Framework which centres digital literacy as a core skill alongside reading, writing and numeracy. Formal education is provided over the first 10 years of school to help develop this skill. This learning continuum covers six elements: practising digital safety and well-being, communicating and collaborating, investigating, creating and managing and operating (187). Each element has a sub-skill such as managing online privacy, creating content and interpreting data. This training is **not specific nor** focused on health literacy but will likely enhance consumers' ability to engage with digital health information and tools.

Consumers

The ADHA has prioritised the development of a Consumer digital health Literacy program to be launched at the end of the 2022-23 financial year (188). The first phase involved consultations with over 14 000 consumers across various events and education programs. The program is currently in its second phase to be delivered over two years. This phase involves the design, implementation and tailoring of the core curriculum for various consumer groups such as Aboriginal and Torres Strait Islander populations, Youth, people with chronic conditions etc. There is also a particular focus on tailoring services for intersectional older Australians such as LGBTIQ+ elders and culturally and linguistically diverse groups.

Most other measures taken to address health literacy thus far have been undertaken on an ad-hoc basis or the initiative of the consumer, healthcare professional or relevant government bodies. Many are conducted in collaboration with or with support from the ADHA (*). Some of these initiatives are outlined in Table 4.2 below.

Table 4.2. Initiatives to Improve Digital Literacy in Australia

Organisation	Type	Target Population	Initiatives
Good Things Foundation*	Charity	People aged 18 years and over	- Training for community organisations across Australia to deliver the **Health My Way** program (190) - The program was designed to help adults develop essential digital skills such as accessing and using My Health Record, finding reliable information and using m-Health Outcomes: - 232 digital health mentors trained - Multiple online courses developed - > 6000 people engaged in workshops and events - External evaluation of the program found it increased learner's knowledge and confidence in

			engaging digital health services and information
Australian Library and Information Association*	Professional Association	Public	- Train library staff to help library users and the public navigate Commonwealth digital health initiatives, particularly My Health Record - Assists public libraries deliver webinars and workshops to their local communities to understand health information and digital initiatives Outcomes - Trained > 2500 library staff - Created resources for public access here.
Be Connected	Common-wealth Government	People aged 50 years and over	- Focused on older Australians who have little to no experience with technology - Examples of lessons taught include how to use digital devices, online security and navigating My Gov, an online secure portal to access government services. Outcomes - Be Connected website with easy-to-understand information on these topics - Created a partner network of community organisations trained to help Australians with their digital literacy

Health Professionals

The ADHA has also prioritised upskilling the health workforce, including clinical and non-clinical staff, on how to use digital technologies to provide safe and quality care. A Workforce and Education Roadmap has been developed to this effect. The roadmap identifies opportunities for the growth of health literacy skills in the workforce. These opportunities include creating digital champions of Executive boards and senior officials, equipping champions with necessary resources to develop health literacy competencies and sharing education resources for the practical implementation of digital health tools. Appendix C of the Roadmap provides more information about digital health initiatives delivered to upskill health workforces (up to September 2020).

Multiple initiatives have been introduced to address workforce education:

- The ADHA has spearheaded the development of online learning courses specifically for health professionals who are using My Health Record. The specific course has been created for different settings and sub-specialties. These courses provide easy-to-understand information about clinician rights and obligations, privacy, and security concerns as well as how to use "My Health Record". These courses can be accessed for free here.
- Similarly, the Australian Alliance for AI in Healthcare has created four flagship programs designed to help clinicians and consumers successfully implement AI-enabled health tools into patient care. The Alliance is a collaboration between almost 100 partners in academia, policy, industry, and consumers. The workforce program coordinates the implementation of AI tools in health care by helping key communities understand the risk,

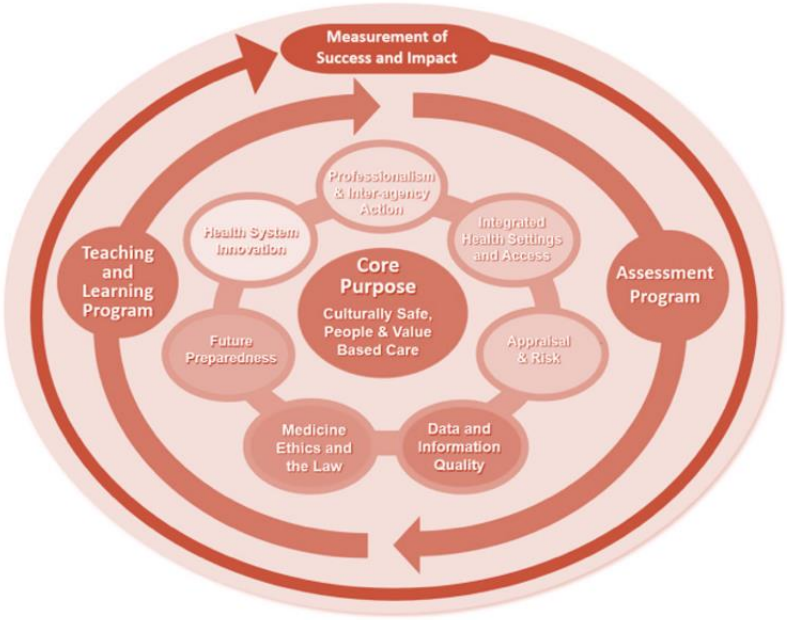
challenges and biases associated with AI-enabled care. Key communities involved in the program are researchers, health service leaders and clinicians (172).

- The Centre for Culture, Ethnicity, and Health also delivers health literacy training courses to health professionals working with migrants and refugees from culturally diverse backgrounds. It has also created a health translations directory in collaboration with the Victorian government that has translated health information into over 100 languages. It also advocates for plain language use by health professionals across Australia on Drop the Jargon Day (190).

Furthermore, the AMC has developed a digital health in Medicine Capability Framework to align medical education with national strategic goals, specifically the development of a digitally skilled health workforce. This framework describes key behaviours, knowledge and experiences needed to perform in a digitally enabled workspace especially as there is a large gap between interest and expertise in digital health. The AMC has created a model to illustrate how digital health should be incorporated into medicine (see Figure 8).

The core purpose is to deliver value-based care through digital technologies to help secure equity in patient care and outcomes. The seven domains outline the focus areas for medical education to ensure doctors can deliver digital health. Each domain has three sub-domains setting learning outcomes. For example, health system innovation has three learning outcomes focused on recognising the current state, future state and continuous improvements to digital health and the implications of these changes for patient care. The AMC recommends that education programs enlist various strategies, including webinars, observation opportunities and self-directed learning, to help build workforce capabilities in medicine. It also emphasises the importance of incorporating assessments into education programs to identify workforce readiness to adopt digital health.

Figure 8. Digital Health Model in Medicine (163)



6. DIGITAL HEALTH REIMBURSEMENT IN AUSTRALIA

Reimbursement for Medical Services and Pharmaceuticals

Health System Funding

Health spending in Australia represents about 10% of the Gross Domestic Product (160). In 2016 – 2017 Australia spent AU$181 billion on healthcare. Funding for the health sector comes from four areas including government, individuals, private health insurers and non-government organisations discussed in detail below:

The Government

All levels of the Australian Government contribute to funding the health system nearly AU$181 billion (160). The federal government contributes approximately 41% to the total cost of healthcare in Australia, and the state and territory governments contribute approximately 27%. The federal government funds the majority of spending on medical services and subsidised medicines, and in 2016 – 2017, it also funded the majority of the AU$5.5 billion spent on health research. The state and territory governments fund most of the spending on community health services. The two levels of government work collaboratively to fund most public hospital services.

Individuals

Approximately 17% of health system funding comes from individual Australians (160). Although the MBS subsidises medical services for individuals who are enrolled in Medicare, not all service providers charge the amount for a service listed on the MBS. As a result, there can be a difference between the MBS rebate and the amount the patient is asked to pay out-of-pocket for the service (160). There are also some medical services, such as dentistry, that are not covered by the MBS and have to be funded out-of-pocket by individuals.

Private Health Insurers

Approximately 9% of health system funding comes from private health insurers (160). In Australia, individuals can choose to have private health insurance, which allows them to choose health providers outside the public system. Private health insurance can cover hospital treatment as a private patient and general treatment for health services not covered by Medicare such as dental, physiotherapy and optical services. The Australian government incentivises the use of private health insurance by leveraging a Medicare Levy Surcharge for individuals who earn above a certain income and do not have an appropriate level of private hospital coverage. The Australian government provides a means-tested rebate to help subsidise the cost of private health insurance for individuals.

Non-government organisations

Approximately 6% of health system funding comes from non-government organisations like charities, community organisations and not-for-profit groups (160).

Public Reimbursement in Australia

A significant proportion of public funding of healthcare in Australia is distributed via Medicare, which is composed of three funding mechanisms: the Medicare Benefits Schedule (MBS); Pharmaceutical Benefits Scheme (PBS); and the National Health Reform Agreement (NHRA).

Medicare Benefits Schedule

In Australia, many health services are fully or partially funded by the federal government. The list of subsidised services is known as the MBS (6).

The MBS includes a Safety Net, an expenditure threshold so that people who use medical services frequently have reduced out-of-pocket costs. Anyone enrolled in Medicare is eligible for the Medicare Safety Net, which comes into effect when a patient spends over a certain amount in a calendar year to see health professionals or get diagnostics tests (206). In essence, patients who have reached the safety net threshold receive a higher government rebate for out-of-pocket costs for medical services, reducing the costs to the patient.

Pharmaceutical Benefits Scheme

Medicines funded by the Australian government are listed on PBS (7). The PBS helps make the costs of medicines cheaper by limiting the costs Australians enrolled in Medicare pay for any PBS medicine to AU$30 (or AU$6.50 for concessionaries) (160). The remainder of the cost is paid by the Australian government. There are over 5,200 brand

names, generic, biologic, and biosimilar medicines listed on the PBS. All products listed on the PBS have been shown to be safe and effective before they can be sold in Australia.

The PBS includes a Safety Net similar to that in the MBS. The PBS safety net is designed so that when a threshold of out-of-pocket costs is reached by an individual eligible to enrol in Medicare in a calendar year, they receive a higher subsidy on PBS items thus reducing their cost (208).

National Health Reform Agreement

The NHRA is an agreement between the Australian federal government and all state and territory governments. Through this agreement, the Australian Government contributes funds to the states and territories for public hospital services, including services delivered through emergency departments, hospitals and community health settings. The NHRA recognises the states and territories as system managers of public hospitals. As such, the states and territories are responsible for determining the mix of the services and functions delivered in their jurisdiction, and system-wide public hospital service planning and performance. The NHRA sets out conditions for shared funding arrangements between the Australian Government and States and Territories for innovative high-cost medical services such as CAR-T therapy.

7. HEALTH TECHNOLOGY ASSESSMENT OF DIGITAL HEALTH IN AUSTRALIA

National HTA methods and processes

In the Australian regulatory context, HTA is predominantly but not exclusively undertaken at a national level. The Australian Government considers HTA a key tool for delivering a safe, effective and efficient health system that is fiscally sustainable (191). HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system. (231).

The HTA framework that is used by the Australian government is based on international best practices in HTA methods and is broadly structured according to the available public funding programs. These programs are shown in Table 5.1. There are three national HTA committees each with different (but interdependent) responsibilities. Each of these committees is required to assess the available evidence and make judgements regarding the comparative safety, effectiveness, cost-effectiveness and budget impact of the technologies and services within their remit. Each committee then provides advice to the federal Minister for Health regarding whether a technology or service should be publicly funded, and the circumstance under which funding should occur (e.g., limits on the eligible patient population, or limits on co-claiming of similar services). Technologies or services with a high budget impact require Cabinet approval before public funding can be implemented.

Table 5.1 Overview of Australian national Health Technology Assessment committees.

Committee	**Types of Health Technology Assessed**	**Subsidy programs**	**Digital Health HTA**
Medical Services Advisory Committee	• Medical Services (including surgical procedures) • Health Technologies (including implanted and non-implanted medical devices) • Blood products • Investigative services (including imaging, genetic/genomic tests, and tests for screening)	• Medicare Benefits Schedule • National Product List (for blood products) • National Health Reform Agreement (for high cost highly specialised therapies) • Other programs, as appropriate	Yes – but limited to technologies that are regulated by the TGA
Pharmaceutical Benefits Advisory Committee	• Medicines • Vaccines • Medical nutritional products	• Pharmaceutical Benefits Scheme • National Immunisation Program	Not to date
Prostheses List Advisory Committee	• Prostheses (implanted and non-implanted medical devices) • Human tissue products	• Prostheses List	Yes – but limited to technologies that are regulated by the TGA and eligible for funding by Private Health Insurers

Digital health technologies assessed by TGA and MSAC

The Australian government does not have stand-alone processes for the HTA of digital health technologies, and currently considers applications for public subsidy via standard HTA pathways. The Medical Services Advisory Committee (MSAC) has responsibility for assessing technologies (including digital technologies) that are regulated by the TGA (192). The TGA regulates software-based medical devices, including software that functions as a medical device in its own right, and software that controls or interacts with a medical device either from within the device or externally. Digital health technologies that are regulated by the TGA include devices that:

- provide a diagnosis or screen for a disease or condition.
- monitor the state or progression of a disease or condition, or the parameters of a person with a disease or condition.
- specify or recommend a treatment or intervention.
- provide therapy through the provision of information.

To reduce the regulatory burden on manufacturers many digital health devices are exempt or excluded from regulation by the TGA. An exemption has also been introduced for some clinical decision support software. Examples of digital health technologies ***excluded*** from TGA regulation (and hence currently excluded from national HTA):

- Consumer health and wellness products not intended to manage serious conditions.
- Behavioural change or coaching software for improving general health parameters.
- Patient-recorded outcome measures and patient surveys that replace paper-based versions of these.
- Software that replicates paper-based mental health assessments in electronic format.
- Communication software that enables telehealth consultations or supports a clinician in making a remote diagnosis (e.g., via a video conference facility and/or transfer of health information from a health professional to their patient).
- Software intended to administer or manage health processes or facilities, rather than patient clinical use cases (e.g., processing of financial records, claims, billing, appointment schedules, business analytics, admissions, practice and inventory management, utilisation, cost-effectiveness, health benefit eligibility, population health management, and workflow).
- Medical image storage and retrieval software, or software that facilitates the communication or transfer of medical images between devices.
- Software intended to be used by health professionals to provide alerts or additional information (e.g., pharmacy dispensing systems and prescribing software used by GPs).
- Software embedded in the delivery of health services such as clinical workflow and support systems that display medical information about a patient or peer-reviewed clinical studies and clinical practice guidelines.
- Chat-based triage software intended to guide users to the most appropriate form of help based on their medical symptoms.
- Laboratory software that facilitates the electronic transfer of data between medical devices.
- Software that calculates a drug dosage based on the dose information provided on that drug's label.
- EMRs and EHRs.
- Data analytics that are class- or group-based rather than individual-patient-based.
- Laboratory information management systems and laboratory information systems such as software that allows a laboratory to automate workflows, integrate instruments, and manage samples and associated information, through to delivery of a report.

Whilst there are currently no clear national assessment pathways for digital health technologies that fall outside the remit of the TGA, HTA of some of the technologies listed does occur at lower levels of government, such as by jurisdictional governments or Local Health Districts, before investment decisions being made.

MSAC processes and methods in general and specific to digital health technologies

MSAC is supported by two technical sub-committees:

i. The PICO Advisory Sub-committee (PASC), and
ii. The Evaluation Sub-committee (ESC)

The role of PASC is to define the question(s) for public funding. The majority of MSAC HTA Reports are guided by the PICO Framework, which focuses on identifying the relevant population(s) [P], defining the intervention [I], and identifying the most relevant comparator(s) [C] and outcomes [O]. The PASC process typically involves a period of stakeholder consultation (public or targeted) and the resulting protocol for the HTA Report is published as a *Ratified PICO Confirmation* document on the MSAC website. The subsequent HTA Report is required to adhere to the *PICO Confirmation* or provide sound justification for any differences.

The role of ESC is to critically appraise the clinical evidence, economic analyses, and budget estimates provided in the HTA reports and to identify key issues (including any legal, ethical or social issues) for consideration by MSAC. Applicants can elect to prepare an HTA Report themselves (referred to as an ADAR, or applicant-developed assessment report; previously referred to as a Submission-Based Assessment or SBA), or to have the government commission an independent HTA group prepare the HTA report (referred to as a DCAR, or Department Contracted Assessment Report; previously referred to as a Contracted Assessment or CA). If an applicant elects to prepare an ADAR, the department will commission an independent HTA group to critique the report and produce an ADAR Commentary. Regardless of the assessment pathway selected by the applicant, all relevant documents are considered by ESC.

MSAC considers applications for technologies and services that may have a therapeutic and/or investigative purpose. By comparison, PBAC and Prostheses List Advisory Committee (PLAC) only consider technologies and services with a therapeutic purpose. Until last year, MSAC published two Guidelines for applications: one for Therapeutic Services and one for Investigative Services. The 2021 update of the MSAC Guidelines (194) merged all the technical guidance into one document to reduce duplication of information across the guidelines. However, despite the recency of the update to the MSAC Guidelines, they currently contain very limited information specific to assessing digital health technologies.

The MSAC guideline information specific to digital health technologies is limited to a discussion of multifactorial algorithms and the difference between fixed or static algorithms (where the learning occurs before the dissemination of the technology) and dynamic algorithms (where learning continues after the dissemination of the technology). As stated in the Guidelines (TG 15.5), the assessment of an investigative technology containing a multifactorial algorithm follows a similar approach to the assessment of a typical investigative technology, but has some additional considerations that need to be addressed:

- The biological plausibility of the algorithm. Include information to support the link between the variables used in the algorithm (clinical or genetic characteristics) and the purpose of the algorithm (diagnosis of a disease, prognosis of a disease, or prediction of response to treatment).
- The output of the algorithm. Algorithms tend to report continuous or discrete scores, but their interpretation may require a threshold. Explain how the score is used and define the threshold for different actions.
- The precedent steps for using the algorithm (to generate the raw data for the algorithm). These may include a gene panel or a radiograph. Explain whether these steps are standardised across all providers of the service and the risk to the accuracy of the algorithm should the precedent platforms differ. Describe the quality assurance approaches to ensure standardisation of the data generation.

Applicants are requested to provide details of the process of developing the algorithm (e.g., key variables, the ways the variables are combined, and weights assigned to different variables), with a clear description of the training step versus the validation step. Importantly, the performance of the algorithm cannot be quantified if the algorithm proposed for reimbursement, or the algorithm assessed in the validation study differs from the algorithm defined by the training dataset. Any changes that are made to the algorithm after the initial HTA will require re-assessment based on additional evidence from subsequent validation studies. This is because changes to the algorithm over time may have a significant impact on the safety and effectiveness of the technology.

Examples of multifactorial algorithms considered by MSAC include:

- A 50-gene signature assay for predicting breast cancer recurrence (Prosigna®), MSAC application number 1473 (194)
- A prognostic RT-qPCR test run locally for ER+ve /HER2-ve breast cancer that determines the risk of early and late metastasis in node-negative and positive cancer under endocrine treatment (EndoPredict®), MSAC application number 1408 (195)
- A 70-gene microarray mRNA gene expression profile breast cancer signature to quantify the risk of disease recurrence and predict adjuvant chemotherapy benefit (MammaPrint®), MSAC application number 1376 (196), and

- Gene expression profiling of 21 genes in breast cancer to quantify the risk of disease recurrence and predict adjuvant chemotherapy benefit (OncotypeDX®), MSAC application number 1342 (197)

The role of PLAC in the assessment of digital health technologies

The PLAC is responsible for approving items for listing on the Prostheses List (PL). The stated role of the PL is to ensure that privately insured Australians have access to clinically effective medical devices that meet their healthcare needs. The role of the PLAC is closely aligned with the roles of the TGA and MSAC: broadly, the TGA assesses medical devices for clinical effectiveness and safety; MSAC assesses the comparative safety, effectiveness and cost-effectiveness of the medical device and sets a benefit for the *service* associated with the device (i.e. the MBS fee; for example, the surgical procedure to implant the device); and PLAC then determines whether the medical device itself should be included on 'Part A'[2] of the PL and sets the amount to be paid for it (i.e. the PL benefit).

The PL benefit is the price paid by private health insurers to hospital providers for prostheses provided to privately insured patients as part of an episode of hospital treatment or hospital-substitute treatment. The treatment can be delivered to a private patient in a private or public hospital. The PL arrangements are intended to have the PL benefits paid by private health insurers relative to clinical effectiveness.

Given its alignment with MSAC methods and processes (the update to the PLAC guidelines that is currently underway will cross-reference the MSAC Guidelines for all HTA methodology), the HTA undertaken by PLAC for digital health technologies is also restricted to technologies regulated by the TGA. The role of PLAC in assessing digital health technologies is further restricted by the fact that the PL is limited to products with a therapeutic purpose, and generally to products that are implanted (although the latter restriction is currently under review by the Australian government). This means that digital health technologies used *solely* for the purpose of screening, diagnosis, monitoring, or treatment planning are generally outside the remit of PLAC. However, there are some exceptions which can be included in 'Part C' of the PL, which currently includes insulin infusion pumps, cardiac ablation catheters, and remote monitoring devices for cardiac devices.

Examples of digital health technologies that are in scope for PLAC include products such as:

- Cardiac Implantable Electronic Devices (CIEDs; such as pacemakers and cardiac resynchronisation therapy devices (CRTDs) - some with remote monitoring capabilities).
- Neurostimulation devices such as ear implants for hearing loss, electrodes for deep-brain stimulation for Parkinson's disease, and nerve stimulation for pain management or urinary bladder control.

As shown above, technologies that include both a diagnostic and a therapeutic function (CIEDS with remote monitoring functionality) can fall within the scope of PLAC because of the therapeutic purpose. As discussed in more detail in HTA Case Study 1, the national HTA processes have been able to value and reimburse the therapeutic aspect of CIEDs but valuing and reimbursing the digital health aspects of the technologies has been more challenging (and has not yet been fully resolved).

It should also be noted that once MSAC has undertaken an assessment of the first technology within a specific group of technologies and an MBS item and fee have been defined, there is no requirement for manufacturers of competitor technologies to be assessed by MSAC: if these competitor technologies can be used with the existing MBS item(s) then the assessment of subsequent 'like' technologies bypasses MSAC and goes straight to PLAC[3]. As PLAC does not publish summaries of its decision-making it means that often the only information regarding reimbursement that is available in the public domain is the MSAC report and/or Public Summary Document for the first technology to come to market.

Examples of publicly reimbursed digital health technologies

Software as a Medical Device

Reimbursement Case Study 1 - Remote Monitoring Cardiac Devices

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[2] The PL has three sections: Part A is for implanted devices and is the largest section of the PL; Part B is for human tissue products; and Part C is for products not eligible for Parts A or B, which are included on the PL at the discretion of the federal Minister for Health.

[3] Although this may change as an outcome of the current PL reform activities e.g., all Class III devices may be required to undergo MSAC assessment even if there is an existing MBS item that is appropriate to be claimed.

For patients using private health care services, remote monitoring of implanted cardiac devices is currently reimbursed via three pathways:

1. Reimbursement of the main cardiac device via a listing on Part A of the PL
2. Reimbursement of the associated transmitter via a listing on Part C of the PL, and
3. Two MBS items for the remote monitoring service delivered by the cardiologist: MBS items 11719 (for patients with a pacemaker) and 11725 (for patients with a defibrillator) (see Table 2).

For privately insured patients the cost of the items listed on the PL (e.g., items listed under points 1 and 2 above) will be covered in full by their private health insurer, as it is a condition of listing on the PL that there will be no 'gap payments' or out-of-pocket costs for items covered by PL arrangements.

By contrast, privately practising medical practitioners are free to set their own fees and if their fees are greater than the MBS fee [4] for a specific service, then the difference will need to be covered privately – either by the patient's private health insurer or directly by the patient. Consequently, the MBS fees for cardiac remote monitoring would typically be reimbursed at 85% of the MBS fee, as they are delivered in the outpatient setting. Where remote cardiac monitoring is offered in the public sector, it is typically funded via hospital budgets.

For patients using public hospital services, there is no charge for the service or the device as all public hospital services are provided free of charge unless the patient declares they are privately insured.

Reimbursement Case Study 2 - Melanoma surveillance photography

Although there are no MBS items specifically for melanoma surveillance photography, the service could be delivered via standard consultation items for specialists (e.g., MBS items 105, 110). MBS items also exist for the excision of suspicious lesions (e.g., MBS items 30196, 30202).

Consumer Digital Health

Reimbursement Case Study 3 - Digital Mental Health Services

The Australian Government doesn't have any specific reimbursement scheme for Digital Mental Health Services. However, there is specific guidance from the MBS on delivering Mental Health Services via Telehealth. As of January 1st, 2022, MBS Mental Health Telehealth services included 4 psychological therapy items for clinical psychologist services and 20 focused psychological strategies items for services provided by a psychologist, GP, non-specialist medical practitioner, occupational therapist or social worker (209).

Coupled with this, the Australian Government has invested in initiatives that support access to safe Digital Mental Health Services. The primary initiative for doing this was the development of an App Library for Mental Health: The Head to Health online resource (210). Head to Health is designed to aggregate Digital Mental Health services in one location, to provide consumers access to services from trusted mental health organisations. The Digital Mental Health services on the Head to Health website are provided via. Range of digital health technologies including apps, online programs, phone services, and online forums. It currently has 756 digital mental health resources from Australian organisations (210).

For a service to be listed on Head to Health it needs to be provided by a trusted Australian service provider, be nationally available and either be free, low-cost or publicly funded (210). In the 2021 - 2022 budget, the Australian government committed AU$11.6 million to commence the transformation of the existing Head to Health resource into a comprehensive national mental health platform (211).

Reimbursement Case Study 4 - Health and Wellbeing

Healthdirect is a public company limited by shares, but its shareholders have delegated representatives of the Health Ministers of its funding jurisdictions and are directly accountable to the federal, state and territory governments as shareholders and as customers. It was founded in 2006 by the Australian Government and the governments of the Australian Capital Territory, New South Wales, Northern Territory, South Australia, Tasmania, Victoria, and Western Australia (212). Healthdirect was established to provide a central telephone-based health advice service but has expanded into other areas. One of the services Healthdirect provides is access to a curated App Library for health and well-being (213). All apps listed in the library are from partner organisations, the majority of which are government or

[4] Although the full MBS fee is typically cited, the amount actually reimbursed by the Australian Government is typically 75% of the MBS fee for services rendered to an admitted patient, and 85% of the MBS fee for services rendered to a non-admitted patient.

not-for-profit organisations. Although the App Library promotes apps that are developed by trusted partners, there is a limited selection, and the library has not been updated since 2016.

Health Information Technology

Reimbursement Case Study 5 - Electronic Prescribing

Electronic prescribing is permitted for both PBS and non-PBS prescriptions in the community setting (214). To dispense electronic prescriptions, community pharmacists are responsible for ensuring that the prescription is legally valid (214). This means that it has to have all the details required to be legally valid, and the prescription must conform with the national Electronic Prescribing Conformance Assessment Scheme (215). The ADHA provides guidance to software developers to enable them to build systems that comply with the required electronic prescribing functionality (216).

The reimbursement process for community pharmacists who dispense PBS electronic prescriptions is the same as for non-electronic prescriptions. Each time a pharmacist dispenses a prescription for a PBS medicine they are reimbursed for the PBS-dispensed price less any patient contribution (217). The PBS-dispensed price includes the cost to the pharmacist of procuring the prescription medicine, administration, handling and infrastructure fee, dispensing fees and any other costs the pharmacist is entitled to (217, 218). In Australia, community pharmacists can register for PBS online claims to be reimbursed for prescriptions they dispense (218). If they choose to register for this service, they are paid each week; they will be notified how much they will be reimbursed before dispensing the medicine to the patient; can correct errors in the system immediately; and can get electronic statements instantly through their Prescription Dispensing Software. This system enables collection of comprehensive data on all medicines dispensed on the PBS, increasingly in near to real-time.

Reimbursement Case Study 6 - eHealth Practice Incentives Program (ePIP)

The Australian federal government has an incentives program aimed to encourage general practices to stay up to date with the latest developments in digital health and adopt new technologies as they become available (219). The introduction of these incentives stimulated the early uptake of computerisation in general practice with more than 95% of practices now using some elements. To be eligible for the ePIP general practices must be accredited or register for accreditation against the RACGP standards for general practice (219). Additionally, general practices must ensure their software systems are compliant with the incentive by checking that their software is registered on the ePIP product register (220). To be listed on the ePIP product register software vendors must demonstrate the capacity to meet minimum scope conformance requirements (221). The ePIP product register is designed to ensure software complies with developing general practice products and ensure they integrate with eHealth infrastructure standards such as integrating with the Australian national health record, My Health Record; supporting secure direct messaging; and enabling electronic prescription exchange services.

A key component of ePIP is incentivising general practices to use the Australian national EHR: My Health Record. The ePIP scheme requires GPs to participate in My Health Record unless they meet the exclusion criteria to be exempt from participation (222). As of May 2016, GPs were required to upload patient records to My Health Record for 0.5% of their practice's standardised whole patient equivalent, which is approximately five patient records a quarter for an individual GP (223). GPs are reimbursed quarterly with payment sizes varying depending on the size of the practice, but the maximum payment amount is capped at AU$13,500 per quarter regardless of practice size (223).

Communication Technology

Reimbursement Case Study 7 - Telehealth

The MBS currently has 23 items available to health professionals that allow them to be reimbursed for delivering consults via a phone or video service (133). Of these, 11 are derived fee MBS items, which allow specialists, consultant physicians and consultant psychiatrists to claim an existing service item as a video consult (133). These items can be used by a wide range of health professionals including medical practitioners, nurse practitioners, midwives, practice nurses and Aboriginal Health workers (133).

To be for a video or phone consult to be reimbursable through the MBS (152):

- The patient and specialist are required to be located a minimum of 15km apart at the time of the consultation;
- The specialist must meet all the requirements set out in the individual MBS item number;
- The patient must not be receiving the consult whilst admitted to the hospital;

- The patient must not be located in an Emergency Department;
- The patient must not be a care recipient of a residential aged care facility located anywhere in Australia
- The patient must not be eligible to receive care through the Aboriginal Medical Service anywhere in Australia.

Items for phone and video consults on the MBS are stand-alone, so they do not have an associated item they are billed with (152). Patients cannot be billed for an initial consult face-to-face and initial video or phone consult and can only be billed for one or the other (152). Once an MBS claim has been made for a video or phone item the payment will be made via electronic funds transfer into the specialist's registered bank account (133).

Although not overtly stated in the MBS guides to video and phone consult reimbursement, there is an expectation that specialists will only undertake a consult with a patient via Telehealth when it is safe and clinically appropriate for the health service being provided (165). Additionally, specialists are expected to deliver Telehealth consults following the Code of Conduct or the equivalent of the relevant National Board that governs the specialist's profession (165). There are at least 17 National Boards with codes, guidelines and policies that should be considered when delivering billable Telehealth services (224).

In addition to reimbursement through the MBS, some private health insurers that introduced claimable telehealth items during the COVID-19 pandemic continue to make them available for their members (159). Australians with private health insurance with companies that allow telehealth claims have a range of criteria these types of consults must meet for them to be claimable.

Examples of economic evaluations in HTAs of digital health technologies

Software as a Medical Device

HTA Case Study 1 - Remote Monitoring of Cardiac Devices

The value proposition of the technology

CIEDs is a broad term used to describe technologies that manage cardiac rhythm and include pacemakers, implantable cardioverter defibrillators (ICDs), and CRTDs (18). Most current generation CIEDs include the capability for remote monitoring of cardiac rhythm in patients with one of these devices implanted. When the technology includes remote monitoring capability it typically has four components (19):

- An implanted cardiac device
- A remote sensor device
- Access to a remote service centre
- A data transfer system

Approach to the HTA of this technology

CIEDs have been included on the PL for many years, as have the associated MBS fees to implant, revise, and explant these devices. The first application to MSAC that requested reimbursement for the remote monitoring functionality of a CIED was considered as MSAC Reference 1111 (198) in 2008. At that time, MSAC found the procedure to be safe, but that comparative clinical effectiveness could not be demonstrated, and consequently, an economic evaluation could not be performed. A subsequent application, 1197 (199) was submitted by Biotronik in 2012 and considered by MSAC at their meeting in April 2014. The PICO Confirmation[5] for this application acknowledged that at the time of writing three other manufacturers, Medtronic, Boston Scientific, and St Jude Medical, had registered multiple transmitters for remote monitoring of their CIEDs with the TGA and that additional future registrations were anticipated. Consequently, the proposed MBS items descriptors specified the type of CIED (i.e. pacemaker, defibrillator, resynchronisation device) but were otherwise 'generic' (i.e. were not limited to specific products from different manufacturers). The application *excluded* implantable loop recorders as these devices have no therapeutic function.

At the time the second application was made, CIED monitoring of patients was conducted through regular face-to-face attendances with cardiologists, with diagnostic testing conducted by technicians. Key clinical groups were supportive of the application noting that remote monitoring was particularly applicable to Australia given its geography and difficulty

[5] *Previously known as a Decision Analytic Protocol (DAP)*

in achieving equitable access to medical care in many regional, rural, and remote areas. PASC considered the following key factors that need to be addressed by the applicant to inform the MSAC assessment of cardiac remote monitoring (200):

- All aspects of the remote monitoring system needed to be described: e.g., how cardiologists are alerted to data availability, the systems to ensure regular review, patient follow-up after review, and frequency of in-office visits.
- All aspects of the intervention are described, including the frequency of data transmission and level of automation.
- The range of outcomes included in the analysis of comparative effectiveness and ensuring that the potential for adverse impacts (as a consequence of a reduced frequency of in-office visits) are captured.
- The applicant's proposal to store patient data overseas, and how patient consent for this would be obtained.
- The logistics of payment of the MBS fee: whether it would be paid as an annual fee or as regular instalments, what would trigger these payments, and whether there would need to be any longer-term payments by patients (for the remote monitoring and/or the transmitter – see below).
- The payment arrangements for the transmitter device. At the time of the application the manufacturer reported they were absorbing the cost of the transmitter for private patients but passing the cost on to the public hospitals for public patients.

For the HTA, the comparator was defined as regular in-office (diagnostic) testing conducted by a cardiologist and/or a technician on behalf of a cardiologist. By the time of the second MSAC assessment for cardiac remote monitoring, there were ten (10) randomised controlled trials (RCTs) that collectively enrolled more than 1,800 pacemaker patients (3 RCTs) and almost 17,000 recipients of an ICD or CRT (7 RCTs).

Based on the evidence from these RCTs, MSAC considered remote monitoring to be as safe as a conventional follow-up. This conclusion was based on an analysis of outcomes including adverse events, mortality, inappropriate shocks, hospitalisations, and emergency visits. Although the applicant claimed that remote monitoring improved patient quality of life, it was noted that the available evidence did not support this conclusion. Consequently, it was concluded that remote monitoring was non-inferior to conventional monitoring in terms of comparative effectiveness.

Economic evaluation of this technology

Because the clinical assessment led to a conclusion of clinical non-inferiority, a cost-minimisation approach (CMA) to the economic evaluation was undertaken. Two CMAs were performed, one for the ICD/CRT population and one for the pacemaker population. Remote monitoring was estimated to be cost-saving for the ICD/CRT population (AU$19.51 less per year), and marginally cost-saving for the pacemaker population (AU$0.71 less per year). In both CMAs, the cost of the remote monitoring service was offset by the cost savings from reductions in-office visits.

In addition to the CMAs described above, the applicant included an 'exploratory' cost-effectiveness analysis (CEA) based on data from one of the included RCTs (the IN-TIME trial). This economic evaluation extrapolated 12-month survival data from the IN-TIME trial over a 5-year time horizon and yielded an incremental cost per life year saved of AU$26,270. MSAC noted that remote monitoring may be cost-effective, but the cost-offsets of remote monitoring were uncertain and not all costs were included in the applicant's modelled economic analysis.

In terms of financial impact, the application estimated that the total annual cost to the MBS of cardiac remote monitoring after 5 years of listing would be AU$8.1M for the ICD population and AU$10.6M for the pacemaker population. However, once the projected cost-savings were accounted for, the *net* financial impact to the MBS was projected to be negligible: AU$324,000 and AU$23,000 in year 5 for the ICD and pacemaker populations, respectively.

Outcomes of HTA/decision-making

After considering the strength of the available evidence MSAC deferred their reimbursement decision, and sought more information:

- from PLAC regarding the suitability of the transmitter for listing on the PL.
- from the applicant regarding (a) the potential benefit when remote monitoring replaces in-office monitoring rather than supplements it, (b) the potential need for multiple software packages for the various devices from different manufacturers, (c) the need for further economic modelling to take account of the cost of the transmitter to the healthcare system.

Ultimately, MSAC approved the MBS items listed below and PLAC approved the transmitters for inclusion in Part C of the PL. There are currently twelve (12) separate transmitters listed on the PL manufactured/sponsored by five different companies: Boston Scientific, Biotronik, Medtronic, Microport CRM, and Abbott Medical (201).

Table 5.2 Current MBS items for cardiac remote monitoring

MBS item 11719 IMPLANTED PACEMAKER (including cardiac resynchronisation pacemaker) REMOTE MONITORING involving reviews (without patient attendance) of arrhythmias, lead and device parameters, if at least one remote review is provided in 12 months. Payable only once in any 12 months **Full MBS Fee:** AU$70.60
MBS item 11720 IMPLANTED PACEMAKER TESTING, with patient attendance, following detection of abnormality by remote monitoring involving electrocardiography, measurement of rate, width and amplitude of stimulus including reprogramming when required, not being a service associated with a service to which item 11721 applies. **Full MBS Fee:** AU$70.60
MBS item 11725 IMPLANTED DEFIBRILLATOR (including cardiac resynchronisation defibrillator) REMOTE MONITORING involving reviews (without patient attendance) of arrhythmias, lead and device parameters, if at least 2 remote reviews are provided in 12 months. Payable only once in any 12 months **Full MBS Fee:** AU$200.35
MBS item 11726 IMPLANTED DEFIBRILLATOR TESTING with patient attendance following the detection of abnormality by remote monitoring involving electrocardiography, measurement of rate, width and amplitude of stimulus, not being a service associated with a service to which item 11727 applies. **Full MBS Fee:** AU$100.20

Source: New items for remote monitoring of cardiac implantable loop recorder devices – Quick reference guide: MBS Online

The proposed reforms to the PL include reductions in price for many CIEDs. In March 2022 the Medical Technology Association of Australia (MTAA) and the then Minister for Health released a Memorandum of Understanding (MOU) that set out a proposal to review the funding arrangements for medical devices via the PL (202). A key commitment in the MOU was an agreement to postpone the planned price reductions for CIEDs for 12 months (to 1 July 2023) until a review of the funding arrangements for the services associated with these devices has been completed. Specifically, this time is to allow for '*MSAC deliberations on the value of the technical support services* [that accompany the supply of CIEDs]. As part of the MOU, MTAA undertook to '*take all reasonable steps to ensure that cardiac companies that produce CIEDs commit to engaging with MSAC… and provide MSAC during its deliberations… with company data relevant to the MSAC process*'.

HTA Case Study 2 - Melanoma Surveillance Photography

Value proposition of the technology

Melanoma Surveillance Photography (MSP) uses conventional total body photography as well as dermoscopic photography (digital dermoscopy). Dermoscopy reveals features of the skin not visible through normal lighting and magnification. It does not however use any form of radiation or exposure other than polarised visible light (203). TBP is performed to photograph all the body regions. Different areas of the body are photographed in standard poses to give approximately 25 "long shot" photographs and all the existing naevi can be seen in those photographs. Once the body shots are performed individual melanocytic naevi are photographed up close (macro images) and then added through the dermatoscopy i.e. a non-invasive, in vivo technique used for examining cutaneous lesions. This includes all pigmented lesions of any size that have any irregularity. It also includes all naevi and pigmented lesions on the body approximately ≥3mm in lateral diameter. In many cases, there are more than 100 individual macro and dermoscopic photographs taken of a single individual.

In Australia, it is recommended that individuals at high or very high risk of melanoma are kept under surveillance for life. Standard surveillance for these individuals typically involves clinical examination by a dermatologist or GP once or twice a year, supplemented with self-examination at home. The intended use of MSP is to enable standardised, repeated MSP for an individual over their lifetime (with a proposed surveillance interval of 5 years) with the goal of early detection and treatment of malignant skin lesions. The digital photography aspect of MSP could theoretically be performed at home by the individual or a carer. Those who would benefit from MSP would have their TBP and digital dermoscopy images performed *in addition* to usual surveillance with TBP and digital dermoscopy is routinely done as a baseline and repeated as per the attending dermatologist's recommendations.

Approach to the HTA of this technology

An application (number 1356) requesting an MBS listing for MSP was received by the Department of Health in 2017, with the Australian College of Dermatologists and the Australian Melanoma Research Group as co-applicants. The application originally sought reimbursement for people in the high-risk or very high-risk category for melanoma, but this was later restricted to people in the very high-risk category only. The MBS item descriptor proposed by the applicants specified that MSP could be performed by a dermatologist or a 'melanographer' (a registered nurse with further training in MSP).

The applicants proposed that the service would be performed by a dermatologist as an adjunct to measures already employed in current clinical practice. The assessment report included three relatively small retrospective cohort studies of MSP in a tertiary care setting which suggested the intervention resulted in increased detection of invasive melanoma of between 30% and 42%. MSAC was uncertain that such high rates of detection failure were representative of current Australian practice. MSAC also highlighted some methodological and transitivity issues with the included studies.

Economic evaluation of this technology

Based on the benefits and harms reported in the evidence base, the application proposed that, relative to standard of care (without MSP), MSP has non-inferior safety and uncertain effectiveness for patients considered at a high risk of developing melanomas. The applicant submitted a CEA that compared MSP in a specialist dermatology setting versus standard surveillance, from the Australian health system perspective. A summary of the economic evaluation is provided in the table below.

Table 5.2 Summary of the economic evaluation of digital photography and dermoscopy for melanoma surveillance (204).

Perspective	Australian Health System
Comparator	Standard care in the community
Type of economic evaluation	Cost-effectiveness evaluation
Sources of evidence	Indirect comparison of a prospective single-arm study and population-based linked data
Time horizon	10 years in the model base case
Outcomes	QALYs
Methods used to generate results	Markov model
Health states	Patient presents for surveillance, dead from other causes, dead due to melanoma, recurrence of melanoma, stage III disease, stage IV disease
Cycle length	12 months
Discount rate	5%
Software packages used	TreeAgePro 2017

The submitted CEA was a revised version of a previously published economic evaluation (205). Revisions were made to:

- The cost of MSP - adjusted to reflect the proposed MBS fees
- The cost of new cancer immunotherapies - added to the model.
- The MBS items were updated from 2013 feet to 2017 fees.

Results of the economic evaluation indicated that MSP in patients at very high risk of melanoma is more effective and less costly than standard care: in other words, MSP dominated standard care. The base case analysis estimated that MSP was associated with a negative incremental cost of AU$8,386 and an incremental gain of 0.21 Quality Adjusted Life Years (QALYs). A one-way sensitivity analysis indicated that MSP dominates standard care up to a threshold of AU$1,100 for MSP per patient annually. Beyond that threshold, specialised surveillance with MSP becomes more costly than standard care. MSAC noted that the key drivers of the economic model were:

- The probability of excisions in standard care
- The probability of early detection of melanoma by MSP
- Treatment costs for melanoma stage III and IV, and
- The probability of benign excisions in standard care.

The projected budget impact was estimated for two scenarios: 100% uptake and 'moderate utilisation'. MSAC judged the 100% uptake scenario to be infeasible. For the moderate utilisation scenario, it was estimated that the total costs to the MBS associated with the introduction of MBS items for MSP would be in the order of AU$130M per year by year 5 of listing, for high-risk individuals and AU$6.5M per year for very high-risk individuals. MSAC noted that there was a very high level of uncertainty with these estimates.

The full HTA report for this application is publicly available and provides further details of the economic analysis (Section D, pages 77- 89) and budget impact analyses (Section E; pages 90 – 96) (206).

Outcomes of HTA/decision-making

After considering the strength of the available evidence concerning comparative safety, clinical effectiveness, and cost-effectiveness, MSAC did not support public funding of melanoma surveillance photography (MSP). MSAC acknowledged that the detection of melanoma was an important issue for Australia but considered that the *incremental* patient-relevant clinical benefit of MSP compared with current practice had not been sufficiently established and was highly uncertain.

Given that current practice involves self- and GP examination, TBP and dermoscopy in the specialist setting with rapid follow-up of suspicious lesions, and despite the favourable cost-effectiveness results, MSAC was uncertain regarding how the proposed intervention adds to value to current practice, and hence the clinical need for the procedure.

8. LESSONS LEARNED

Gaps

As is widely acknowledged, digital health is a diverse area that describes many different products and platforms. This has proved challenging for regulators internationally, especially in the context of HTA and reimbursement. A number of gaps exist across the domains considered in this report, as summarised below.

Fragmented support for innovation in digital health

- **Scale-up:** Translating pockets of innovation in the Australian digital health landscape into widespread adoption of health technologies that can enhance existing care models and support new ones. A particular gap exists inequitable access to digital health, particularly for Australians who have limited access to healthcare currently or may be disenfranchised by the uneven adoption of technology in healthcare.
- **Investment:** Dedicated funding for digital health innovation is lacking in Australia, particularly government funding to support the development of commercial products and the commercialisation process for these technologies.
- **Fragmented market:** digital health vendors or service providers do not have a centralised source of information or agency to help navigate the Australian digital landscape. A vendor must appraise separate websites, legislation, and regulations to identify their legal and ethical obligations.

Incomplete connections between HTA and reimbursement

- **National HTA only conducted for a proportion of DHTs:** Whilst MSAC's standards methods and processes have so far been sufficient for assessing digital health technologies that meet the definition of SaMD, the majority of digital health technologies in use in Australia are outside the scope of the MSAC (because of their *regulatory* risk assessment being low and inadequate evidence) and have not undergone any formal HTA.
- **Fragmented funding arrangements:** Australia has a range of reimbursement mechanisms in place for some categories of digital health, such as Telehealth, but there are gaps in other areas. There are currently no public reimbursement mechanisms for Consumer digital health, though some private health insurers have reimbursement mechanisms in this area. Coupled with this there is a lack of clarity around reimbursement mechanisms for SaMD as many of these technologies are currently funded via non-MBS payment models.

Challenges

A fragmented health system

- **Federated government:** Australia has a siloed health system with each jurisdiction releasing its own strategic vision for the future of digital health. While there is a shared goal to coordinate care between jurisdictions, particularly the delivery of the national strategy, each jurisdiction has set different timelines and outcomes and is pursuing them with relative independence.
- Healthcare organisations can implement any digital health technology that conforms to the legislative and regulatory framework. This increases the difficulty of coordinating care as incompatible computer systems can be used across jurisdictions, settings, and specialities.
- The prevalence of SaMD in the Australian digital health Landscape is increasing, but due to varied risk profiles, individual solutions and users' regulation of these technologies is a challenge.

Broad scope of DHTs as a class

- AI is a challenge for many stakeholders in the Australian digital health landscape. Due to the breadth of ways AI can be applied within healthcare and in health technology, it is challenging to regulate and assess. Coupled with this, whilst there is significant research interest in applying AI in healthcare, its potential is yet to be widely realised in healthcare organisations and by the Australian health sector more broadly.
- Although the majority of Australians use technologies such as smartphones, challenges remain in relation to digital health literacy. A particular challenge relates to the development of digital health skills and capabilities in the health workforce. Whilst the need for these skills is described in policy documents, and there are frameworks

describing the knowledge and skills required, translating such policies into practice within the health workforce remains a challenge in the Australian digital health landscape.

Limits of HTA for some DHTs

- **National HTA processes:** The potentially co-dependent nature of digital health may make HTA for interventions seeking pre-market approval in Australia more complicated and time-consuming for the application sponsor. This is due to the fact that multiple committees may need to be involved in the process of assessment. However, it should be emphasised that this is only a challenge for digital health interventions that are co-dependent.
- **Factors that determine the value of digital health technologies**: There are attributes of digital health technologies that are currently not explicitly valued by the HTA frameworks in place in Australia, which tend to focus heavily on health outcomes and not patient experiences of care, or "health system efficiencies" (106).
- **Newer DHTs will challenge current HTA methods**: The rise of dynamic, machine-learning algorithms will challenge the current 'static' approach to HTA: with HTA conducted for an initial investment decision and very limited use of re-assessment to adjust levels of reimbursement. An approach to HTA that is itself dynamic will be needed to respond to these emerging technologies.

Opportunities

Coordination and Collaboration across jurisdictions

- There is an opportunity for each jurisdiction to learn from digital health initiatives successfully implemented in other jurisdictions. For example, HealtheNet can be used by other jurisdictions to pursue their goals of an interoperable and universally accessible EMR for each patient.
- Coordination at a national level can be pursued through the Health Ministers Meeting. This Meeting enables health ministers to coordinate policy and health initiatives across jurisdictions. Recent examples include managing the vaccine roll-out, aged care and dental strategy. This Meeting can similarly be used to coordinate digital health strategies and national law that affects these technologies and services.

Defining Digital Health and understanding risk profiles

- Whilst considerable effort has gone into defining the categories of digital health that require regulation, there is still work to be done to support organisations wishing to enter the Australian market with these technologies. There remains an opportunity for a clearer guidance on the regulation processes, and case studies of different digital health technologies that are and are not regulated.
- There is an opportunity to enhance existing tools to evaluate risk and describe adverse events related to digital health in the Australian market. Current frameworks do not capture risks and adverse events in detail, making it challenging to understand the extent to which these technologies cause harm and put in place safeguards to ameliorate them.

Supporting Digital Health Innovation

- Australia has a considerable opportunity to support the growth of a home-grown digital health industry sector. Unlike traditional medical devices which require specialised manufacturing infrastructure, which is not established in Australia, many digital health innovations are software-based and can be developed locally.
- The growth of Consumer digital health in Australia, particularly Digital Mental Health, presents an opportunity to implement solutions that help Australians identify evidence-based and effective technologies. One approach that may be effective for doing this is to scale up existing solutions that have proved effective such as App Libraries like Head to Health to encompass other Consumer digital health products.

Fit-for-purpose HTA for DHTs

- **DHT-specific HTA framework:** A particular challenge for frameworks that are applied to digital health interventions which many regions including Australia have to consider, is that different classifications of these technologies have different risk profiles and may also offer unique benefits and risks for individual consumers (15). In addition, the DHTs are often utilised in combination with other types of care, for example, in case of CIEDs that include both a diagnostic and therapeutic function.

- **Scope for other entities to undertake HTA of DHTs:** There is scope for other levels of government to undertake HTA to inform investment in DHTs at more local levels. HTA undertaken by these entities could take account of the factors described above.

Conclusion

In conclusion, the exploration of digital health within the Australian landscape reveals both challenges and opportunities that necessitate strategic action for advancement. Identified gaps encompass fragmented support for innovation, incomplete connections between HTA and reimbursement, and a fragmented health system. Challenges arise from the broad scope of DHT's and current methodology to assess them mainly due to evolving nature if technology. However, amidst these challenges lie opportunities fir coordination and collaboration across jurisdictions by defining digital health and understanding the risk profiles clearly. This in turn will support the digital heath innovation and establish fit-for purpose HTA frameworks that can assess value for money for DHTs. By embracing these opportunities an addressing the outlined challenges, Australia can navigate the complexities of the digital health landscape and foster innovation, accessibility and effectiveness in healthcare delivery.

GLOSSARY

Term	Description
Electronic prescribing	Electronic prescribing enables prescribes to lawfully dispense a prescription electronically (124). This prescription must be issued by a clinical information system conformant to government legislation (225).
Image-based prescribing	Special COVID-19 pandemic arrangements enable patients to be lawfully dispensed a prescription by providing a digital image or copy of a prescription provided by an authorised prescriber (124).
HealtheNet	An eHealth NSW initiative to connect computer systems across different settings to ensure health professionals have timely access to patient health information (226).
Medical devices	Any instrument, software, appliance or other article intended to be used for diagnosis or treatment of a disease, injury or disability, psychological state, control of conception or in vitro examination (227). A full definition is section 41BD in the *Therapeutic Goods Act 1989* (Cth).
My Health Record	An online summary of key health information for health consumers. It brings health information together from consumers, healthcare providers and Medicare (113).
Software-based Medical Devices	Software-based medical devices include software that controls another medical device or satisfies the definition of medical devices independently.
Telehealth	A remote consultation between health professionals and consumers using a telephone (228).
Virtual Care	Digital health technologies connect patients with health professionals at a time and location of their choosing. Technologies include telephone, video conference or remote monitoring. These connections can be synchronous or asynchronous (229).

ABBREVIATIONS

Term	Description
ACCC	Australian Competition and Consumer Commission
ACL	Australian Consumer Law
ACT	Australian Capital Territory
ADAR	Applicant Developed Assessment Report
ADHA	Australian Digital Health Agency
ADII	Australian Digital Inclusion Index
AI	Artificial Intelligence
AIDH	Australian Institute of Digital Health
AMC	Australian Medical Council
AMSANT	Aboriginal Medical Services Alliance Northern Territory
APPs	Australian Privacy Principles
CA	Contracted Assessment
CCA	Competition and Consumer Act 2010
CEA	Cost-effectiveness Analysis
CEO	Chief Executive Officer
CIEDs	Cardiac Implantable Electronic Devices
CMA	Cost-minimisation approach
CRTDs	Cardiac resynchronisation therapy devices
CTH	Commonwealth
DCAR	Department Contracted Assessment Report
EHEC	eHealth Executive Council
EHRs	Electronic Health Records
EMRs	Electronic Medical Records
ePIP	eHealth Practice Incentives Program
ESC	Evaluation Sub-committee
GPs	General Practitioners
HHSs	Health and Hospital Services
HTA	Health Technology Assessment
ICD	Implantable cardioverter defibrillators
ICT	Information and communications technology
MBS	Medicare Benefits Schedule
mHealth	Mobile Health
MHRV	Mental Health Reform Victoria
MOU	Memorandum of Understanding
MRFF	Medical Research Future Fund
MSAC	Medical Services Advisory Committee
MSP	Melanoma Surveillance Photography
MTAA	Medical Technology Association of Australia
NHRA	National Health Reform Agreement
NSW	New South Wales
NSQDMH	National Safety and Quality Digital Mental Health
NSQHS	National Safety and Quality Health Service
NT	Northern Territory
OAIC	Office of the Australian Information Commissioner

PASC	PICO Advisory Sub-Committee
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PHNs	Primary Health Networks
PL	Prostheses List
PLAC	Prostheses List Advisory Committee
Privacy Act	Privacy Act 1988 (Cth)
RACGPs	Royal Australasian College of General Practitioners
RCTs	Randomised Controlled Trials
QALYs	Quality Adjusted Life Years
SA	South Australia
SaMD	Software as a Medical Device
SBA	Submission-Based Assessment
SCV	Safer Care Victoria
SFIA	Skills Framework for the Information Age
TBP	Total Body Photography
TGA	Therapeutic Goods Administration
The Goods Act	Therapeutic Goods Act 1989 (Cth)
The Rule	Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 (Cth)
VAHI	Victorian Agency for Health Information
WA	Western Australia

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Appendix 1. Regional regulatory frameworks

New South Wales (NSW)

eHealth NSW is a separate organisation embedded within the NSW Ministry of Health (67). It is responsible for all ICT and digital infrastructure as well as eHealth strategies, policies and standards. This includes the implementation of the *eHealth Strategy for NSW Health 2016-2026*. Other responsibilities include standardising data structures and information management across the state, managing funding plans, promoting a culture of innovation and developing capabilities and skills to sustain eHealth initiatives (28).

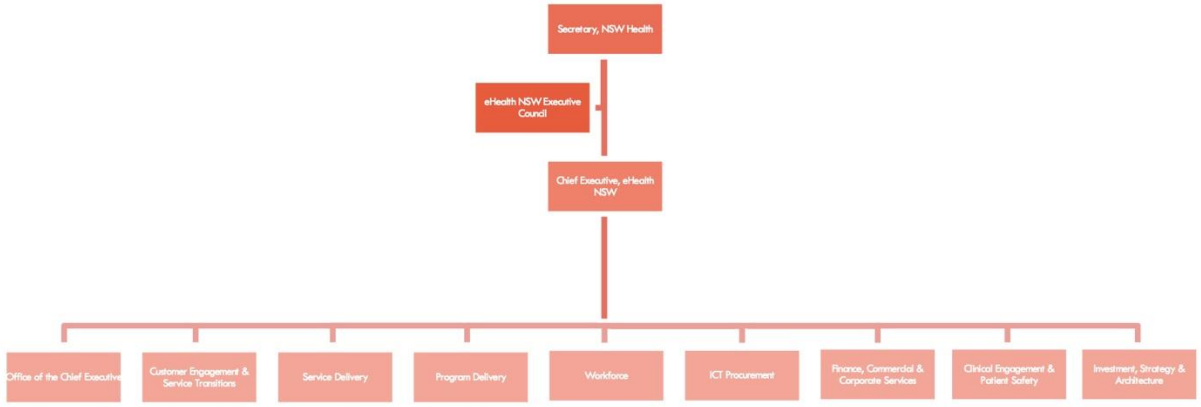
eHealth NSW also has a specific responsibility to create a feedback loop with relevant stakeholders. This feedback loop involves consultations and active participation of stakeholders, particularly patient and carer groups, that inform policy development, design, and prioritisation of eHealth initiatives. It also engages and collaborates extensively with Local Health Districts, Specialty Health Networks, Pillars, and Agencies to support the implementation of eHealth initiatives, and ensure compliance with standards supporting a state-wide culture of innovation. Districts, Networks, Pillars and Agencies are also responsible for establishing local eHealth governance structures, procuring local systems and tailoring state-wide eHealth strategies and systems to the community (28).

There are fifteen Local Health Districts covering eight metropolitan regions and seven rural and regional areas. There are also three Specialty Health Networks. Two Networks focus on children and paediatric services and justice health and forensic mental health (68). The third network covers public services delivered by three private hospitals part of St Vincent's Health Australia. These Districts and Networks have a responsibility to maintain public health in their communities and manage public hospitals, health institutions and services to facilitate efficient patient care. There are individual governing boards responsible for "the strategic direction and operational efficiency" of each District and Network (68). While most responsibilities are limited to each geographical area, there is an additional responsibility to cooperate with other Districts and Networks. The Pillars are various agencies, bureaus and institutes that support health services and patient care in NSW. The five Pillars are the Agency for Clinical Innovation, Bureau of Health Information, Cancer Institute NSW, Clinical Excellence Commission and the Health Education and Training Institute. A more detailed breakdown can be found here (69).

eHealth NSW is advised by the eHealth Executive Council (EHEC). The EHEC has representative membership of various Chief Executives in NSW Health including eHealth NSW, the Minister of Health, the Clinical Excellence Commission and more. This is the peak body for information and communications technology (ICT) and eHealth. It is also responsible for setting strategies, providing policy advice and monitoring eHealth performance and project delivery (70). The EHEC is supported by the NSW Government ICT Board.

eHealth NSW is answerable to the NSW Health Secretary who is responsible for managing and setting the strategic direction of the NSW health system (69). This includes monitoring health system performance, implementation of health policy and the NSW Health budget. The Secretary is directly responsible to the Ministers for Health and Mental Health. These Ministers and the Health Secretary are supported by the NSW Ministry of Health in the performance of their executive and statutory functions (71). The Ministry provides core funding for eHealth initiatives and monitors their delivery. It also helps coordinate care across jurisdictions and between public and private organisations. Figure 2 depicts the NSW organisational structure.

Figure 2. NSW Organisational Structure (72)

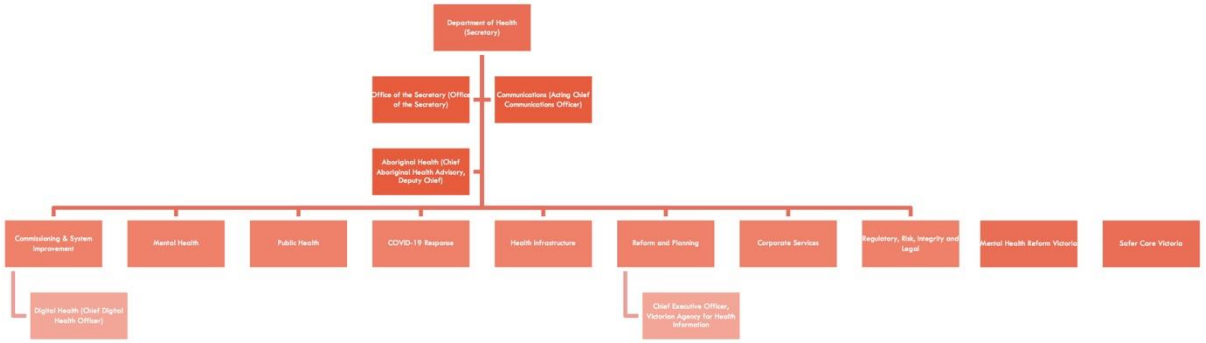


Various NSW Government Agencies help support the implementation of the eHealth Strategy by identifying opportunities for cross-agency ICT integration and information sharing. Likewise, NSW Health will collaborate with other jurisdictions to create core clinical systems interoperable across jurisdictions and ensure alignment with the National digital health strategy. NSW Health encompasses all state health services, and shared services including eHealth NSW, Local Health Districts, Specialty Networks and Pillars. NSW Health also collaborates with the Commonwealth Department of Health to align policies, funding and eHealth initiatives across different settings and organisations (28).

Victoria

Governance and stewardship for Victoria's Digital Roadmap are spread across four domains and nine pillars of digital health maturity. The oversight for this Roadmap is provided by the Department of Health. Figure 3 illustrates the organisational structure of the Department of Health.

- *Figure 3. Organisational Structure of the Department of Health (73)*



The Department of Health is overseen by the Secretary who is responsible for all six health divisions, three agencies and three service teams. The divisions include Aboriginal Health, Commissioning and Service Performance, Mental Health, Public Health, COVID-19 Response and Health Infrastructure. Each division is overseen by a chief executive and has sub-committees, service committees and boards overseen by a senior official. For example, the digital health board is answerable to the Commissioning and System Improvement division head. The three service teams concern Reform and Planning, Regulatory, Risk, Integrity and Legal and Corporate Services. The wide ambit of these services teams primarily covers governance, regulations, policies, and strategies that govern health services and reform in Victoria. Examples of sub-committees include legal privacy and integrity, audit and risk, finance, people and culture, system reform and planning and intergovernmental and research.

The digital health branch works with health services to implement digital initiatives such as multifactor authentication, privacy and security software, training packages and clinical-grade network (11). It is also responsible for assuring all Health ICT projects with budgets above AU$1 million. This assurance commences with an analysis of engagement and terms of reference for digital health products and services. A report with recommendations for further review is produced and an action plan is developed to ensure compliance with regulations. The digital health Board then monitors the

implementation and progress of the action plan (11). The Branch is also tasked with exploring the feasibility of an online appointment scheduling system and personalised healthcare navigation assistance.

The Department of Health also collaborates with the PHNs to implement the Roadmap (11). There are six PHNs responsible for coordinating primary and community health care in Victoria.

There are three other agencies involved in health care, the Victorian Agency for Health Information (VAHI), Safer Care Victoria (SCV) and Mental Health Reform Victoria (MHRV). VAHI is an integrated agency in the Department of Health responsible for collating and delivering information to inform decision-making in health care. It is particularly responsible for providing information on health services quality and safety to health divisions, chief executives, clinicians, agencies, researchers and the Victorian public (74). It also collaborates and supports SCV to ensure "timely quality and safety information"(75) is made available to health services. SCV helps health services use past experiences to improve healthcare quality and safety. This is achieved through collaborations with clinicians and consumers, data analytics, the development of best-practice guidelines and targeted projects and training (76). It also oversees three independent bodies that monitor patient death and harm, including voluntary-assisted dying, perioperative care, and obstetric and paediatric mortality and morbidity. Lastly, the MHRV is responsible for implementing the recommendations of the Royal Commission into Victoria's Mental Health System (77).

Queensland

Queensland has 16 hospitals and health services (HHSs) that are responsible for digital health strategy roll-out in their communities. These HHSs are independent statutory services governed by their CEO and Health Board (78). HHSs have separate service agreements with the Department of Health which outline what and how health services, research and training are to be delivered by the HHS as well as funding arrangements for those services. These agreements also include outcomes to be achieved and performance measures. Service agreements are negotiated for three financial years and current agreements can be accessed here (79).

The Department of Health and its activities are overseen by the Director-General. The Department consists of seven divisions (e.g., Corporate Services, Prevention, COVID-19 Response, Aboriginal and Torres Strait Islander Health etc.) and three services including Clinical Excellence Queensland, Queensland Ambulance Service, and eHealth Queensland. eHealth Queensland provides HHSs and the Department of Health advice about eHealth innovation, strategy, standards, and infrastructure. This includes the delivery of eHealth initiatives and customer support for telehealth, mobile devices, network and security (78).

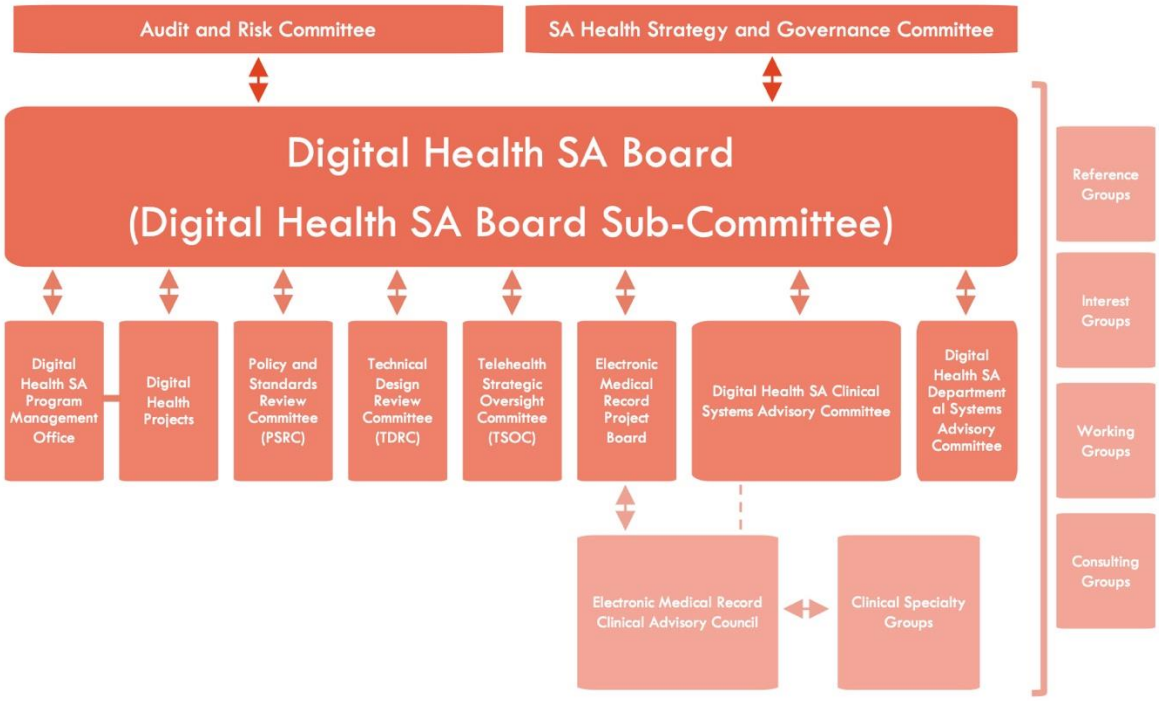
Queensland Health has also committed in its digital health vision to collaboration and consultations with consumers, clinicians and various partners including other statutory bodies, jurisdictions, and private sector organisations (12).

Queensland also has a digital health Improvement Clinical Network that is responsible for providing digital clinical strategic direction to Queensland Health and co-ordinating digital health initiatives (80). It is currently focused on enhancing current digital health initiatives, improving user experience, and fostering clinical communication across the health ecosystem. It is overseen by Clinical Excellence Queensland. The Chief Information Officer for Queensland Health and the Deputy Director-General of eHealth Queensland who leads the ongoing transformation of Queensland's public health service through the delivery of innovative and customer focussed ICT platforms and services.

South Australia (SA)

The *Digital Health Governance and Investment Framework Policy Directive (81)* outlines information on the policies, governance arrangements and processes for digital health investment. It applies to the 10 Local Health Networks that comprise the SA Health System. These networks manage the delivery of health services in their communities and are each managed by their own Governing Board. Lead by a CEO, the Board monitors the quality and performance of health services, maintains health infrastructure and collaborates with health professionals and consumers for community planning (82). These Governing Boards are answerable to the SA Minister for Health and Wellbeing. Figure 4 shows the organisational structure of the digital health arm of SA Health.

- *Figure 4. South Australia's Governance Model for Digital Health (81)*



The Digital Health SA Board provides "strategic direction and operational oversight" for all digital health initiatives and investments in information communication technologies (81). It is also responsible for setting and enforcing digital health strategies. It has established a sub-committee with delegated authority to support the Board including reviewing the performance of existing and new digital technologies and services. The sub-committee also provides governance oversight for various committees, project boards and advisory committees and councils.

There are two advisory committees, clinical and departmental systems, that provide advice and recommendations on new initiatives. Matters concerning patient care, clinical quality and safety are referred to the clinical advisory committee while corporate-related questions about information and communication technology systems are referred to the departmental systems advisory committee. Various project boards provide further oversight and monitor outcomes for individual projects. Three operational committees help sustain the use of digital initiatives within SA Health. The Policy and Standards Review Committee determines policies and standards applicable to information and communication technologies. The Technical Design Review Committee ensures the efficiency, effectiveness, and compatibility of digital initiatives with health standards and infrastructure. The Telehealth Strategic Oversight Committee is responsible for promoting the uptake and sustaining use of telehealth services. The Program Management Office (yellow) supports the implementation of digital health initiatives, achievement of targeted outcomes and benefits realisation (81).

The Board, sub-committee, advisory and operational committees are overseen by the SA Health Strategy and Governance Committee and the Audit and Risk Committee. The former committee provides operational guidance for the entire SA health system. The latter ensures policies, architecture and initiatives adequately manage health risks by assessing the implementation and use of digital health technologies (81).

Western Australia (WA)

The WA Department of Health as the "System Manager" provides governance oversight for the delivery of the state's digital strategy. It is responsible for all clinical and non-clinical systems, digital health initiatives, digital standards and policies (14). HHSs is a shared service centre that supports the System Manager in the execution of their responsibilities. It provides procurement, ICT and workforce services to staff across the public health system in WA. A Program Implementation Support Unit will also support the Manager by monitoring the state-wide implementation of outcomes in the digital health strategy. This includes tracking progress, and risk factors and identifying successful programs (14).

The strategy also commits to collaborating and consulting advisory groups consisting of health service providers, consumers and industry representatives when introducing systemwide initiatives and procuring new technologies. Health service providers are also empowered to take charge of the local implementation of the digital health strategy under the *Health Services Act 2016* (14). The flexibility introduced by this piece of legislation enables clinical staff to adapt initiatives to the needs of their local community. The strategy also contemplates introducing a digital health panel responsible for creating a procurement shortlist.

Tasmania

The Tasmanian Government is responsible for developing digital infrastructure to support the delivery of outcomes outlined in *Digital Health Transformation*. It is also responsible for adopting cohesive and comprehensive digital strategies and fostering a digital culture across government staff and agencies. The Department of Health is responsible for the delivery of digital health initiatives. The Department is responsible for public healthcare services delivered in the community and provides advice to the Minister of Health (45).

The Secretary is responsible for all services and programs delivered by the Department of Health. Their job includes employing experienced staff, managing consumer complaints, and creating a safe work environment. The Secretary also advises public health services, the Health Minister and other government agencies (83). The Director Office of the Secretary supports the Secretary in the execution of their responsibilities. A Health Executive consisting of various Chief Officers from across the Department of Health also advise the Secretary and their Office.

Executive subcommittees, answerable to the Health Executive, provide clinical and consumer representation, monitor outcomes and risks, and evaluate program delivery. There are also various executive teams responsible for business decisions at a local level. Their discretion is limited by directions provided by the Secretary, Health Executive and Executive subcommittees. The Secretary also directly consults clinical, industry and consumer advisory groups when deciding on health services, policies, and standards. These groups will provide independent feedback and public and staff education to support the implementation of digital health initiatives.

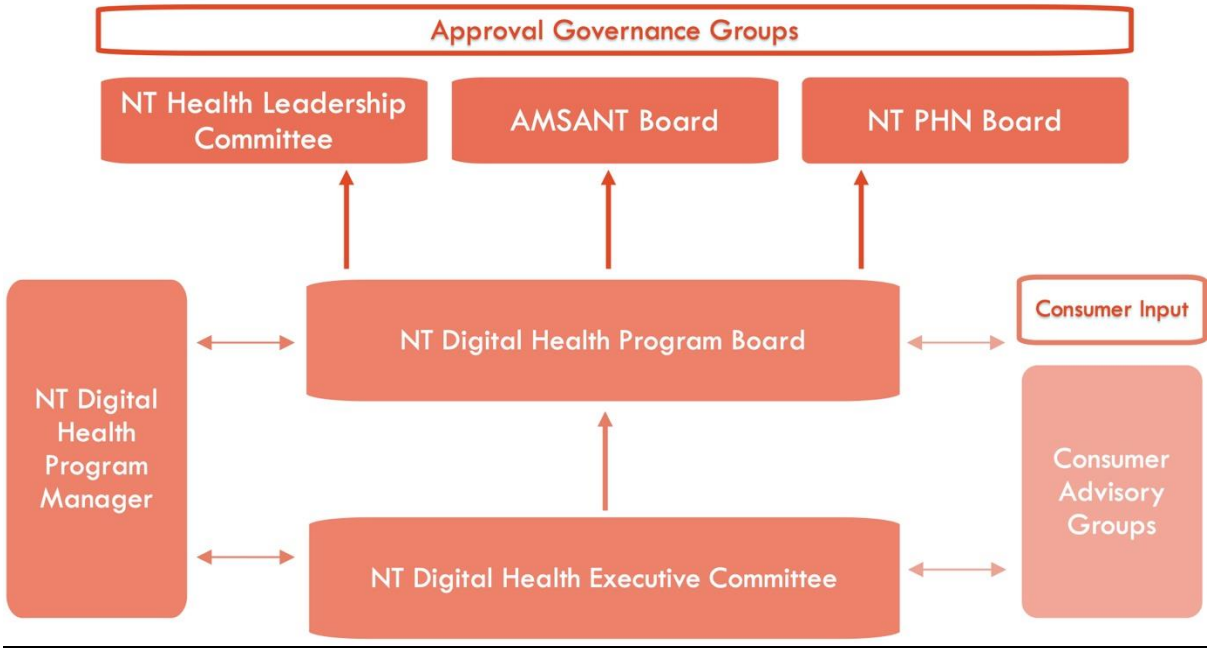
Other partners for the execution of the *Transformation* are Primary Health Tasmania, other governments and jurisdictions, peak bodies, colleges and the ADHA. Primary Health Tasmania will be involved to engage clinical staff in the development, implementation, and evaluation of digital health services (45). It will also be engaged to promote digital health initiatives among community health service providers. Collaborations with ADHA will help support the implementation of health initiatives in Tasmania and provide necessary resources for the development of effective digital solutions. Likewise, collaborations with local governments in Tasmania and other jurisdictions will help integrate care across Australia (45).

A more detailed breakdown of the organisational structure can be found on pages 38-40 of the Strategy.

Northern Territory (NT) (13)

NT Health, Aboriginal Medical Services Alliance Northern Territory (AMSANT) and NT PHN formed a collaborative partnership to drive and coordinate digital health initiatives. Answerable to this partnership is a Program Board that oversees the delivery of the digital health strategy. This Board consists of the CEOs of all three organisations who approve initiatives, infrastructure, and funding in accordance with the strategy. An Executive Steering Committee oversees the delivery of programs approved by the Board. The Board and Steering Committee are supported by a Program Manager who is responsible for managing day-to-day activities in pursuit of strategic outcomes. A consumer advisory group has also been established to advise the Board and Steering Committee to consult and collaborate on digital health initiatives. Figure 5 shows the inter-relationships between these groups.

Figure 5. Partnership Collaborative Governance Model (13)



Australian Capital Territory (ACT) (51)

There are three bodies responsible for the delivery of the ACT Digital Health Strategy: ACT Government, ACT Health Directorate and Digital Solutions Division. The ACT Government sets health policies and provides funding for digital health programs. It also monitors the activities of the Health Directorate and Digital Solutions Division. The Health Directorate provides governance oversight and ensures digital health programs and strategies are aligned with other health priorities. It is also responsible for developing a digitally ready workforce. The Digital Solutions Division delivers programs to build digitally enabled models of care in collaboration with clinical staff. It is also responsible for appointing Chief Information Officers for Medicine and Nursing.